

EXHIBIT 606

Keith Patrick Gibson

June 14, 2011

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UNITED STATES DISTRICT COURT OF THE
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLES DIVISION

* * *

IN RE: DIGITEK PRODUCT LIABILITY)
LITIGATION)

THIS DOCUMENT RELATES ONLY TO:)
Kathy McCornack, an individual;)
Daniel E. McCornack, Jr., an)
individual; and Ralph J.)
McCornack, a minor by and through)
his guardian ad litem,)

Plaintiffs,)

vs.)

ACTAVIS TOTOWA, LLC, et al.,)
Defendants.)

Case No. 2:09-cv-06

DEPOSITION OF KEITH PATRICK GIBSON, Pharm.D., J.D.

San Luis Obispo, California

Tuesday, June 14, 2011

9:00 a.m. - 12:26 p.m.

REPORTED BY CINDY D. GRIFFITH
CSR #7281

Keith Patrick Gibson

June 14, 2011

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UNITED STATES DISTRICT COURT OF THE
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* * *

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Plaintiffs,)

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ACTAVIS TOTOWA, LLC, et al.,)
Defendants.)

Case No. 2:09-cv-06

Deposition of Keith Patrick Gibson, Pharm.D.,
J.D., produced, sworn and examined on the 14th
day of June, 2011 between the hours of
9:00 a.m. to 12:26 p.m. at the offices of
McDaniel Shorthand Reporters, in the County of
San Luis Obispo, State of California,
before Cindy D. Griffith,
Certified Shorthand Reporter, within the
State of California.

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I N D E X

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WITNESS

EXAMINATION BY

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Keith Patrick Gibson, Pharm.D., J.D.

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FOR THE DEFENDANTS:

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A Report of Keith Patrick Gibson, Pharm.D., J.D.
dated May 16, 2011

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B Notice of Deposition

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C Global RPH.com document

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D "Postmortem Redistribution of Digoxin in Rats"
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E "Post-mortem Clinical Pharmacology"
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F "Mechanisms Underlying Postmortem Redistribution
of Drugs: A Review" by Pelissier-Alicot

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G "Estimating Antemortem drug concentrations
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postmortem redistribution" by Cook and Braithwaite,
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1 KEITH PATRICK GIBSON, PHARM.D., J.D.,
2 having been first duly sworn, was
3 examined and testified as follows:
4

5 EXAMINATION

6
7 BY MR. MORIARTY:

8 Q Tell us your full name.

9 A My full name is Keith Patrick Gibson;
10 G-i-b-s-o-n.

11 Q And do you go by doctor or mister?

12 A Um, whichever you prefer.

13 Q Okay. Have you given testimony before?

14 A I have.

15 Q How many times?

16 A Not very many. Two, three.

17 Q Well, you've been a lawyer.

18 A I'm a lawyer.

19 Q You've been an administrative law judge.

20 You've been a witness. So you know the rules; correct?

21 A Thank you.

22 Q If you don't understand my question, let me
23 know. I will make it clear to you. Okay?

24 If you need to refer to a document, get that
25 document and refer to it.

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1 A Okay.

2 Q In the medical-legal setting, do you know the
3 difference between possibility and probability?

4 A More probable than not? Is that what you're
5 asking?

6 Q Yes.

7 A Yes.

8 Q You understand that?

9 A Preponderance of the evidence.

10 Q So possible is 50-50 or less, something that's
11 speculative.

12 Now, I want you to assume that Dan McCornack
13 took no Digitek that was outside of its specifications.
14 Okay?

15 What, in your opinion, was the cause of his
16 death?

17 MR. ERNST: Objection.

18 MR. MORIARTY: That's all you're allowed to
19 say. Thank you.

20 Q What's your opinion?

21 A Well, if he took no nonconforming tablet, then
22 I think it's the opinion of both the pathologist and his
23 treating physician that he died from Digoxin poisoning
24 is probably okay. I would assume it probably was.

25 I have a problem with that sort of assumption

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1 because he's been on that drug regimen for such a long
2 time, and nothing particularly changed in his -- either
3 his drug regimen or his life. I mean he's a 40-year-old
4 man.

5 Q I understand your position. I've read your
6 letter.

7 A Fine.

8 Q I'm just asking simple questions. I just need
9 a simple answer to my simple question.

10 MR. ERNST: Objection. Objection. There's no
11 question pending. Argumentative.

12 BY MR. MORIARTY:

13 Q So even assuming he took no
14 out-of-specification Digitek, you still believe to a
15 probability that Digoxin toxicity led to his death;
16 correct?

17 MR. ERNST: Objection.

18 THE WITNESS: I thought that's what you just
19 told me.

20 MR. ERNST: Objection. Compound.

21 BY MR. MORIARTY:

22 Q Go on.

23 A Do you want me to answer it?

24 Q Yes.

25 A I'm used to somebody making a ruling. So

1 excuse me if I'm delaying.

2 Well, not really. I don't think he would have
3 died if he hadn't had a nonconforming tablet. I think
4 he would have survived. I don't see where the Dig level
5 went up. He does have multiple reasons for having
6 elevated Dig level, though.

7 Q I'm asking a very simple question. Assume he
8 took no nonconforming Digitek; right?

9 A All right.

10 Q That they were appropriately dosed, and he took
11 them according to his morning and evening schedule. Do
12 you have an opinion as to the cause of his death?

13 MR. ERNST: Objection.

14 BY MR. MORIARTY:

15 Q To a reasonable degree of medical probability?

16 MR. ERNST: Objection; multiples.

17 BY MR. MORIARTY:

18 Q Go on.

19 MR. ERNST: It's compound, vague.

20 THE WITNESS: No.

21 (Defendants' Exhibit A was marked for
22 identification.)

23 BY MR. MORIARTY:

24 Q Thank you.

25 In your report, which I have had marked as

1 Exhibit Gibson A, you have a lot of footnotes and
2 there's a lot of literature in there; right?

3 A Correct.

4 Q Have you read any additional literature about
5 Digoxin, Digitek or postmortem redistribution that you
6 didn't either footnote in the body of the report or list
7 on page 10?

8 A Can I ask you if your question implies that at
9 the time I wrote the report, or since I wrote the
10 report?

11 Q At any point.

12 A Yes.

13 Q What have you read since?

14 A Well, I didn't really anticipate that you would
15 ask that question, but I'm constantly looking at books
16 and pulling up internet sites when I'm at the hospital,
17 all around.

18 Last night I spent some time on the internet
19 looking at different articles. I found another article.
20 And so I --

21 Q Well, the notice of deposition tells you to
22 bring everything you reviewed to form your opinions.
23 Okay?

24 A But internet stuff I can't bring.

25 Q Well, if you printed it, you did.

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1 A If I printed it, I have it.

2 Q I want to see everything you reviewed --

3 A This is --

4 Q -- since you wrote this report, Exhibit A.

5 A Well, since I wrote that report, Exhibit A,
6 it's all been on the internet so I cannot bring it.

7 Q Tell me what websites.

8 A Oh. That's a very difficult question. Because
9 I do a Google search, and last night I was just doing
10 random Google searches for symptoms of Digoxin toxicity,
11 and, you know, I got a list of page up in the Google
12 notes, and I was just clicking on them, going back and
13 forth. A lot of them are Pub Med, for instance.
14 There's all kinds of different sites.

15 Q So you didn't print any of it?

16 A No, no. I printed this.

17 Q This is Dr. Gallenter's article about
18 "Mechanisms, Manifestations and Management of Digoxin
19 Toxicity"?

20 A That's the only one I printed since I wrote
21 that report.

22 Q Do you remember the name of anything else
23 specifically that you reviewed since writing the report?

24 A No, I do not remember.

25 Q Okay. I'll get back to this later.

1 Now, in all of the reading that you have done
2 to prepare for your opinions for this report and for
3 this deposition today, have you found a single piece of
4 peer-reviewed medical literature, toxicological
5 literature, that says that you can reliably predict an
6 antemortem serum Digoxin level based on a postmortem
7 whole blood draw?

8 MR. ERNST: Objection.

9 You can go ahead and answer the question.

10 THE WITNESS: Thank you.

11 Well --

12 BY MR. MORIARTY:

13 Q First, yes or no?

14 MR. ERNST: No. He gets to answer his
15 question.

16 MR. MORIARTY: I said first yes or no. I want
17 to know where he's going with his answer, Don.

18 MR. ERNST: Objection.

19 MR. MORIARTY: I can tell he's going to make
20 speeches all day. Okay? I want to know yes or no, and
21 then you can explain. I'm not cutting off your answer.

22 MR. ERNST: You are not in control of this
23 deposition. You ask the questions. He gets to answer
24 appropriately. You cannot dictate how he's going to
25 answer the question.

1 MR. MORIARTY: Let him lecture for a while and
2 then I'll call the judge.

3 MR. ERNST: You were lecturing first.

4 BY MR. MORIARTY:

5 Q What's your answer?

6 MR. ERNST: I'll have the question reread.

7 THE WITNESS: No.

8 BY MR. MORIARTY:

9 Q Your answer is "no"?

10 MR. ERNST: I'll have the question reread.

11 BY MR. MORIARTY:

12 Q Do you have any estimation?

13 A Do we want to read the question?

14 Q I know the question. You said no.

15 Do you have any explanation that you want to
16 add to your answer about that?

17 A Well, numbers do give you guidance in the
18 picture of what you are looking at when you look at a
19 patient with numbers. You can't play the numbers
20 exactly because the pharmacokinetics don't devolve that
21 way.

22 In this particular case, you have one data
23 point, and you can't make a whole bunch of assumptions
24 based on one data point. That's not real science. To
25 extrapolate backwards, you can't do that with any

1 reliability to get an exact number. But postmortem Dig
2 levels do tell you things, and those things are valuable
3 things to know.

4 Q Okay.

5 MR. ERNST: He's not done answering your
6 question.

7 BY MR. MORIARTY:

8 Q Were you done?

9 A Well, I could keep going, but I'll let you ask.

10 Q I'm asking one question at a time.

11 MR. ERNST: You should feel free to answer that
12 question completely.

13 THE WITNESS: Do you want me to continue?

14 MR. ERNST: Please continue answering that
15 question.

16 BY MR. MORIARTY:

17 Q My question was, did you find a piece of
18 literature, and he already answered it.

19 A Well, I did --

20 Q I'm going to be here for hours. You'll get a
21 chance to explain everything in this report. Okay? And
22 at the end, I guarantee you --

23 MR. ERNST: If you want to make speeches rather
24 than ask questions --

25 MR. MORIARTY: Don.

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1 MR. ERNST: -- I will call the judge.

2 MR. MORIARTY: Don, at the end you always ask
3 questions. You can clarify whatever you want. Trust
4 me. You'll get his opinions on the record. I'd like to
5 do this in an orderly fashion according to the questions
6 I ask.

7 MR. ERNST: Matt.

8 MR. MORIARTY: We've been through this with at
9 least three medical depositions so far.

10 MR. ERNST: Matt, if you wish to behave in this
11 manner, I will call the judge.

12 MR. MORIARTY: Fine.

13 MR. ERNST: You have given more speeches than
14 asked questions.

15 So, I will have the last question that he
16 answered reread.

17 If you have anything else to add, Mr. Gibson,
18 finish answering your question, please.

19 THE WITNESS: And I should --

20 (Record read.)

21 MR. MORIARTY: The question was whether he
22 found a single piece of peer-reviewed medical
23 literature. I'm just giving her reference, Don.

24 (Record read.)

25 MR. ERNST: The second part of that question

1 was you have an explanation I want to add. And then you
2 can continue.

3 THE WITNESS: Well, I did make a mistake in
4 that I don't know if it's reliable or not, but Vorpaul
5 and Kohl, which is an article that I referenced in my
6 report, didn't try to make some correlation backwards.
7 Whether that's reliable or not, I don't think it is. I
8 mean, I think Dig levels with postmortem redistribution
9 do tell you stuff, but I don't think you can extrapolate
10 backwards on one data point.

11 BY MR. MORIARTY:

12 Q All right. When were you retained as an expert
13 in this case?

14 A It was a long time ago.

15 Q Do you have --

16 A I could --

17 Q -- any correspondence from Mr. Ernst in your
18 box that indicates when he first sent you material or
19 when he called you on the phone or anything else?

20 A I do have a bill I sent to him from 2009. Will
21 that do?

22 Q Sure.

23 Do you think this is the first invoice?

24 A I believe that to be the first invoice, yes.

25 Q It says, "Initial contact, August 26th, 2009."

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1 Correct?

2 A Correct.

3 Q And then review of materials, et cetera?

4 A Those are billing events. I mean, Mr. Ernst
5 probably saw me in the courthouse and asked me could I
6 come by and --

7 Q I understand.

8 A But that's --

9 Q This is ballpark; right?

10 A Yes.

11 Q Thank you.

12 A You're welcome.

13 Q So in your report, which is Gibson Exhibit A,
14 in the first paragraph, it says, "At your request I'm
15 providing my opinion on the postmortem drug levels found
16 in Mr. McCornack's blood"; correct?

17 A Correct.

18 Q "The distribution of Digoxin and other drugs
19 postmortem"?

20 A Correct.

21 Q "The effect of differing formulations of
22 Digoxin on bioavailability" --

23 A Correct.

24 Q -- "and the resulting clinical picture that is
25 the likely cause of Mr. McCornack's death."

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1 Did I read that all correctly?

2 A You read it correctly.

3 Q Is that, essentially, what you were asked to do
4 in this case?

5 A That's what I was essentially asked to do in
6 this case, correct.

7 Q So, during your work on this case, did you
8 undertake to ascertain whether Dan McCornack suffered
9 from Digoxin toxicity before he died?

10 A Okay. I have a little bit of a hearing
11 problem, so can you kind of -- you had a soft word
12 there.

13 I think your question --

14 Q I'll repeat it.

15 A Okay.

16 Q Did you undertake, as part of your work in this
17 case, to ascertain whether Dan McCornack suffered from
18 Digoxin toxicity --

19 A Okay.

20 Q -- before he died?

21 A Yeah. Well, what I was --

22 Q Is that a "yes"?

23 MR. ERNST: He's going to --

24 MR. MORIARTY: I need to understand what he
25 said. He said "yeah."

1 THE WITNESS: Yes.

2 MR. MORIARTY: I need to understand.

3 Q Now you can explain.

4 A So what I reviewed was the depositions that I
5 was given, which are of his wife, and I reviewed the
6 deposition of the two doctors. Um, I saw some medical
7 charts and medical records.

8 Q Did you undertake to ascertain whether
9 Dan McCornack died from Digoxin toxicity?

10 A I don't quite understand what you mean by did I
11 try to ascertain that.

12 The opinion of the pathologist was that he had
13 died from digitoxicity. The opinion of his treating
14 physician was that.

15 I thought my role was to determine whether or
16 not there's enough science to back up their opinions as
17 to whether or not this dose and this kind of clinical
18 picture could substantiate their opinions.

19 Q Well, on page 9 of your report, it says,
20 "Therefore it is my opinion that, judging from
21 Mr. McCornack's clinical condition on the night of
22 March 23rd, 2008, Digoxin poisoning was the cause of his
23 death."

24 A That's correct.

25 Q You're rendering an opinion on that?

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1 A I'm rendering an opinion based on the opinion
2 of the two physicians that I read the reports on. I'm
3 rendering that opinion based on the clinical picture,
4 the drugs he took, and every other data point that I
5 could ascertain.

6 Q So you undertook to ascertain whether
7 Dan McCornack died from Digoxin toxicity?

8 A The reason I -- it was confusing to me was
9 because I didn't go out physically and collect evidence.
10 I looked at --

11 Q I understand. But what --

12 MR. ERNST: All right. Would you please let
13 him finish answering his question.

14 BY MR. MORIARTY:

15 Q With the information --

16 MR. ERNST: Would you please let him finish
17 answering the question.

18 BY MR. MORIARTY:

19 Q With the information available --

20 MR. ERNST: Would you --

21 MR. MORIARTY: He's not talking.

22 MR. ERNST: He wasn't finished answering his
23 question and you are repeatedly asking another question.

24 BY MR. MORIARTY:

25 Q Were you done with your answer?

1 A Well, I am now. That's okay. It's okay.

2 MR. ERNST: It's not okay.

3 MR. MORIARTY: Okay.

4 Q I'm going to ask this question again.

5 A Please.

6 Q All you have to do is say yes or no.

7 A I will.

8 Q Pause for a few seconds and then I'll move on.

9 MR. ERNST: Or answer the question if it
10 doesn't call for a yes or no.

11 BY MR. MORIARTY:

12 Q From the information that you had in your box
13 that Don Ernst sent to you, you undertook to ascertain
14 and then render an opinion about whether or not
15 Dan McCornack died from Digoxin toxicity; correct?

16 A Yes.

17 Q All right. And that is a diagnosis, isn't it?

18 A Well, my role here is not necessarily to make
19 that diagnosis so much as to support the diagnosis
20 already made by the pathologist and the treating
21 physicians.

22 So I was really asked -- and as you remember
23 from paragraph number 1, I was really asked to determine
24 whether or not there was postmortem drug, what the
25 effects of that would be in redistribution of Dig and

1 other drugs postmortem, whether there's any drug
2 interactions that might have resulted in an increased
3 Dig level whether or not bioavailability.

4 Those are really the opinions that I was asked
5 to do. I mean, I'm supporting, by my findings in every
6 other area, the clinical diagnosis made by the two
7 physicians.

8 Q Okay. Let me make sure I understand this.
9 Because the first paragraph of the letter where you're
10 repeating what your charge was, and the resulting
11 clinical picture that is the likely cause of
12 Mr. McCornack's death?

13 A Correct.

14 Q Right. But --

15 A But that physicians opined, and I was either
16 going to support or not support based on the scientific
17 evidence whether or not those opinions were valid and
18 plausible opinions.

19 Q Does page 9, where you say what your three
20 bullet-pointed opinions are, indicate anywhere that what
21 you are doing is just agreeing with and supporting the
22 opinions of other doctors who have testified?

23 A Well --

24 MR. ERNST: Objection.

25 THE WITNESS: You asked me a question that says

1 does my exact words say exactly what you say. No, they
2 do not. It is my intention to do that.

3 MR. MORIARTY: Okay.

4 MR. ERNST: You can answer that. You can
5 continue.

6 THE WITNESS: I mean my intention was to back
7 up and substantiate the opinions of these two doctors.
8 And quite frankly, I totally agree with their opinions.

9 BY MR. MORIARTY:

10 Q Which two doctors are those?

11 A Well, three doctors. There's Dr. Lemm who's
12 the treating physician, Dr. Von Dollen, which is the
13 cardiologist, then the -- boy, just skipped my mind.
14 The pathologist that I read.

15 Q And it is your understanding that in the
16 depositions of Doctors Lemm and Von Dollen, they have
17 said to a reasonable degree of medical probability that
18 Digoxin toxicity caused the death of Mr. McCornack?

19 A I specifically remember Dr. Von Dollen saying
20 that, yes.

21 Q So how many times have you had your deposition
22 taken?

23 A Two. This will be two.

24 Q What kind of case was the first one?

25 A The first one was about a decade ago and it

1 involved a very strange product known as Lipokinetics.
2 Mr. Mattison asked me to look into the chemistry of this
3 particular product, because his pat- -- his client -- I
4 sometimes call them patients, if you don't mind -- had a
5 liver transplant, and whether or not this drug or this
6 fat burner that was sold by a nutrition store for
7 weightlifters to cut, you know, if you know what to cut
8 means, was the source of her failing liver and her liver
9 transplant.

10 Q When you refer to Mr. Mattison, you're talking
11 about the gentleman who was then the law partner of Don
12 Ernst; correct?

13 A Yes.

14 Q Is that the Mass versus Dexter case?

15 A I don't think so.

16 Q What's the Mass versus Dexter case?

17 A I have no recollection of the Mass versus
18 Dexter case.

19 Q Have you ever been a defendant in a lawsuit?

20 A You know, I also did a depo once for
21 Mr. Mattison on a Vicodin case. Yes. I just remembered
22 that.

23 Q All right.

24 A But I don't know the name of that case any
25 longer, it was so long ago.

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1 Q Okay. Have you ever been a plaintiff for a
2 defense in a lawsuit?

3 A Um.

4 Q Plaintiff or defendant in a lawsuit?

5 A Yes. The answer to that is yes.

6 Q Other than a divorce case?

7 A I've never been divorced.

8 I was just recently sued for legal malpractice
9 by a gentleman who sued everybody from the Board of
10 Supervisors, the judges, and included everybody, and my
11 name was listed as a defendant.

12 Q And what was your role? Lawyer, administrative
13 law judge?

14 A I was a lawyer. I represented him for a period
15 of time.

16 Q Where was the case filed?

17 A I believe it was filed in the San Luis Obispo
18 Superior Court.

19 Q And what is the plaintiff's name?

20 A I can't remember right off the top of my head.
21 I could get that information for you.

22 This is a gentleman that had --

23 MR. ERNST: You've answered the question.

24 THE WITNESS: Okay.

25 BY MR. MORIARTY:

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1 Q Ever been sued in any other case?

2 A Not that I can think of.

3 Q I assume that the two prior cases for what was
4 then the Ernst & Mattison firm were for the plaintiff;
5 correct?

6 A Yes.

7 Q How many cases have you tried to verdict?

8 A As a public defender?

9 Q As a lawyer?

10 A As a lawyer. Oh, I don't know. I stopped
11 counting at 100. I don't know.

12 Q How many of them were criminal cases?

13 A All.

14 Q Do you still practice law?

15 A Yes.

16 Q What kind of law do you practice now?

17 A I'm on a panel that serves as the public
18 defender. The public defender -- two -- a law firm has
19 a contract with the county for the service of public
20 defender, and I subcontract with them. I'm currently
21 assigned to Departments 1 and 5 of the superior court
22 for all misdemeanor matters.

23 Q Do you do any civil litigation?

24 A No.

25 Q Have you ever done civil litigation as a

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1 lawyer?

2 A For a year I tried to do some divorces. And
3 periodically, I help people with their small claims
4 actions. No, not as an advocacy lawyer.

5 Q So what is McGuire --

6 A McGuire & Ashbaugh are the two -- the law firm
7 that has the contract with the public -- with the county
8 for the services of the public defender in San Luis
9 Obispo County, and I subcontract with them.

10 Q Do you have your own business entity?

11 A Yes.

12 Q What's the name of your separate --

13 A Just me. Just --

14 Q -- law firm?

15 A -- Keith Patrick Gibson, Attorney at Law.

16 Q It's not a professional corporation?

17 A No.

18 Q Limited Liability Company?

19 A No. Just me.

20 Q So how much of -- are you still an
21 administrative law judge?

22 A Yes.

23 Q And are you still a pharmacist?

24 A Oh, yes.

25 Q Tell me how much of your time -- do you have

1 any other professions currently?

2 A No.

3 Q How much of your time is spent on these three
4 distinct jobs?

5 A I'll do the administrative law judge thing
6 first because that's the simplest. I get about one or
7 two appointments every six weeks. And they are for
8 about a day in which I have maybe anywhere from four to
9 16 cases, depending on what I'm hearing.

10 I'm currently rotating between the
11 California -- the California Men's Colony, the Salinas
12 Valley Prison, and then there's a group of prisons out
13 in Corcoran that I visit. It's a valley town.

14 I'm a deputy public defender assigned to
15 Departments 1 and 5 with another gentleman, and I do
16 every -- I'm assigned to every misdemeanor, me and him,
17 so we kind of split that calendar up, every misdemeanor
18 that comes through Departments 1 and 5. And I'm there
19 Monday through Friday from 9 to 12 every day except for
20 when I'm off doing something else, like this.

21 And then there's sporadic trials that I do.
22 Those usually last three, four days, because they are
23 misdemeanors.

24 I have in the past done felony, but currently
25 I'm in a misdemeanor position.

1 Then I currently work at Marian Medical Center
2 as a staff pharmacist. And I do seven on, seven off,
3 from seven or eight at night to six or seven in the
4 morning. And I start Thursday nights and work for seven
5 days. And I've been rotating that way for every five
6 years now.

7 Prior to that I worked, there's a lot of other
8 hospitals, but that's what I'm currently doing.

9 Q So is there a way to divide that up just based
10 on simple percentages or fractions? Is it a third, a
11 third, a third?

12 A No. The administrative law judge doesn't take
13 a lot of my time.

14 Q All right.

15 A I get to go there. I don't read anything prior
16 to going there. I make my ruling, and I leave and I'm
17 done.

18 The public defender, I'm there Monday through
19 Friday from nine to noon. Then, of course, I've got to
20 answer questions, phones. I've got motions to write and
21 all that kind of stuff.

22 Q Is the ALJ position elected or appointed?

23 A No, it's an assignment. It's not an election.

24 Q Who does the assignment?

25 A It was done 20-some years ago, and I don't

1 really remember who originally assigned me to that.

2 Q What would the process be?

3 A I don't even know what the process was.

4 What happened was I happened to be hanging
5 around when they -- the Keya -- it's for Keya hearings.
6 It's for Keya hearings, which are involuntary medication
7 hearings.

8 I was interested in it because it involved
9 drugs. So it kind of drove me, like moths are alike.
10 So I was hanging around that sort of thing. And somehow
11 some guys got appointed to be defense lawyers, and I got
12 appointed to be -- they asked me to do it, and I said
13 yes, and I was happy to do it, and I enjoy that.

14 Q And then how long have you served as a forensic
15 pharmaceutical consultant?

16 A Well, you know, from the very first day I
17 showed up in court, people found out I was a pharmacist,
18 they've been asking me questions, and so it was really
19 kind off the cuff, for the most part.

20 At some point about ten years ago, I decided
21 that I was no longer going to do that, because they
22 asked me to testify. I felt somewhat conflicted by it.
23 And most of the time it would be public defenders would
24 ask me. I felt somewhat conflicted being on the public
25 defender team and then trying to be a neutral expert, so

1 I cut that out, and now I try to redirect those people
2 to people I know that are anxious for that sort of work.

3 But the first ten years I did, you know, just
4 off-the-cuff stuff. People would ask me questions just
5 walking down the hall.

6 I mean, I could tell you anecdotal stories if
7 you --

8 Q No.

9 I want to know how much of your time is spent
10 as a forensic pharmaceutical consultant.

11 A I try to do very little. It's almost none.

12 This case I took on in 2009. And, you know, I
13 will do cases that are interesting. This was an
14 interesting scenario that I -- so I did take it on.

15 Q So, in California, is there a license for
16 something called a forensic pharmaceutical consultant?

17 A No, not that I know of.

18 Q Is there a separate educational path for that?

19 A Oh, I think there is a university in Florida
20 that has an educational path for that, but I don't -- I
21 didn't engage in that. They have a master's degree or
22 something in that range.

23 Q Is there a certification, or a certificate for
24 forensic pharmaceutical consultant?

25 A No.

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1 Q I assume that this is a title, just a title?

2 A Just something I made up to put on the
3 letterhead. I thought it was fairly descriptive,
4 though. I've kind of stuck with it because it tells you
5 exactly what I do.

6 Q Do you have any other forensic pharmaceutical
7 consultant projects going right now?

8 A None.

9 Q When was the last time, other than this case,
10 that you had one?

11 A Oh, boy. Quite a few years ago. I don't know
12 if I could remember.

13 I mean, other than the questions I get down the
14 hallway, which are always happening, I try to at least,
15 for the last five years I have another gentleman who
16 takes a lot of these. He's willing to do this work, and
17 so I refer them to him.

18 Q Have you ever done any consulting work for a
19 pharmaceutical company?

20 A No.

21 Q Have you ever been an employee of a
22 pharmaceutical company?

23 A Not that I know of.

24 Q Do you advertise your services as a
25 pharmaceutical -- forensic pharmaceutical consultant?

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1 A I do not.

2 Q Have you ever been excluded as a witness from a
3 case?

4 A I have not.

5 Q Now, I assume that since you've not worked for
6 pharmaceutical companies, you have no hands-on
7 experience in pharmaceutical manufacturing?

8 A Other than compounding the pharmacist does
9 while at work.

10 Q That's not manufacturing, is it?

11 A That's correct.

12 Q You don't have any hands-on experience in
13 pharmaceutical quality assurance?

14 A I have no hands-on experience.

15 Q Do you have any hands-on experience in
16 pharmaceutical regulatory matters?

17 A No hands-on experience.

18 Q What is the extent of your experience of the
19 contact with the FDA?

20 A I've never contacted them.

21 Q Do they contact you?

22 A Never.

23 Q Do you have to file reports to the FDA?

24 A Well, there is an adverse drug reaction report
25 that I've filed a few times. It's a form --

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1 Q NAER; correct?

2 A I've done that a few times. But the problem
3 with my life is that it's more of an outpatient type
4 thing and I suppose my type is inpatient.

5 So rather than fill out that form, a lot of
6 times you fill out adverse drug reaction forms in the
7 hospital in their own internal monitoring systems. I've
8 done that more times than the opposite.

9 Q Have you ever filed an adverse drug event form
10 for Digoxin?

11 A No.

12 Q Does your pharmacy dispense Digoxin?

13 A It does.

14 Q Did your pharmacy dispense Digitek?

15 A The current pharmacy does not.

16 Q Well --

17 A To the best of my knowledge.

18 Q Well --

19 A Where I currently work.

20 Q The drug has not been sold since it was
21 recalled in April of 2008.

22 A Okay.

23 Q I'm asking for pharmaceutical work that you did
24 prior to 2008, did you ever dispense Digitek?

25 A I do not know.

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1 Q Did you ever find, among any Digoxin solid oral
2 dose products that you did dispense, any extra thick
3 tablets?

4 A Um, my experience in retail pharmacy is very
5 limited.

6 In the hospital they are already in a dose
7 packaged. And currently, I touch very little product
8 because of the nature of my work now.

9 Q When you say unit dose packaged, are you
10 talking about blister packs?

11 A Yes. Well, and some we make ourselves. Most
12 hospitals today are either using Omnicell or some
13 product like that. The product is all stuck into
14 shelves. The nurse comes up, puts a patient's name in.
15 That drawer opens, that kind of thing.

16 Q But just to clarify my question. Either a
17 tablet that you and your staff handled --

18 A I've never seen that.

19 Q -- or something coming back from the floor,
20 Hey, Mr. Gibson, this looks funny?

21 A Right.

22 Q You've never seen a double-thick tablet in your
23 pharmacy experience?

24 A No.

25 Q Did you ever have occasion to send tablets to a

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1 laboratory for potency evaluations?

2 A I never did, no.

3 Q Anybody that you worked with ever did that?

4 A Well, I don't know if Mr. Ernst did that or
5 not. I think he did. But I never personally, or any of
6 my roles as a pharmacist, we never did that.

7 Q You've never done it in a nonlitigation
8 setting?

9 A That's correct. You're talking about Digitek?

10 Q I'm talking about --

11 A Digoxin?

12 Q Yes, Digoxin.

13 Have you ever personally -- I'm sorry, let me
14 back up.

15 A Okay.

16 Q Do you have the qualifications and equipment to
17 perform chemical testing on solid oral dose
18 pharmaceutical products such as dissolution and assay?

19 A No, I do not.

20 Q Do you have to be licensed to be a pharmacist
21 in California?

22 A I do.

23 Q And are you licensed in any other states?

24 A I was licensed in Nevada about 15 years ago.
25 But no, not currently.

1 Q Ever had any action taken against your pharmacy
2 license?

3 A Never.

4 Q Ever had any action taken against your law
5 license?

6 A Never.

7 Q I know this is rather obvious, but I have to
8 ask.

9 A Sure.

10 Q I assume from your C.V. you are not licensed to
11 practice medicine in the State of California?

12 A That's correct, I'm not licensed to practice
13 medicine.

14 Q And is diagnosis part of the practice of
15 medicine in the State of California?

16 A It is.

17 Q And you know that if you were to render
18 diagnosis on patients that would be a violation of
19 California code; right?

20 MR. ERNST: Objection.

21 THE WITNESS: If I rendered a diagnosis for
22 treatment, yes, in some ways.

23 But you've got to remember my job involves drug
24 information, and so I cannot particularly divorce the
25 clinical situation, clinical settings or the patient

1 pathologies from my advice that I give to physicians.
2 And quite -- pharmacists also do a lot of drug dosing.
3 You know, in the hospital we're responsible for dosing
4 vancomycin, for instance. I won't go through the litany
5 of stuff that I do. But those things all involve
6 understanding the clinical picture.

7 So I don't -- I don't invite patients to come
8 to see me to render a diagnosis. If I believe that the
9 drug is inappropriately used for incorrect diagnosis, I
10 do point that out. So I'm not totally devoid of any
11 ability to do anything when it comes to diagnosis. But
12 I don't treat patients directly.

13 Q (BY MR. MORIARTY) Are you allowed to recommend
14 vitamins after diagnosing a customer's ailment?

15 A I don't diagnose patients directly.

16 Q Okay.

17 A So, and I don't work retail. And so that
18 problem almost never comes up.

19 Q Have you ever taken any courses, continuing
20 education courses, that involved postmortem
21 redistribution?

22 A No.

23 Q Have you ever taken any courses regarding
24 cardiovascular care?

25 A Yes.

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1 Q What kind of courses?

2 A Well, they were many moons ago. Are you
3 talking about continuing education or as part of my
4 training?

5 Q Let's first start as part of your training.

6 A Yes. I mean, in pharmacy school, we had
7 therapeutic classes all of the time. So they covered
8 every disease and drug state that involved drugs.

9 Q Have you taken continuing education regarding
10 cardiovascular care?

11 A I have. Although I couldn't recite to you
12 currently. In the last four or five years, no, but
13 prior to that, probably.

14 Q Okay. The hospital where you were working in
15 2006, '7 and '8, do you know whether it even had Digitek
16 in its formulary?

17 A That was General Hospital. I left the county
18 hospital in 2004. 2005 I was at Marian Medical Center,
19 and I do not think they have Digitek.

20 Q 2005, '6, '7, and '8 you worked at the same
21 hospital?

22 A I think from 2005 to the present, yes.

23 Q They -- you don't think they ever carried
24 Digitek in their formulary?

25 A I mean, I couldn't say absolutely. But I don't

1 think their formulary includes Digitek, but I don't
2 really know.

3 I just had a conversation with a purchasing
4 person a couple days ago, and she told me that whenever
5 Digitek would come in, she would send it back. But
6 she's now rotated on to be the computer person. There's
7 another person. I didn't ask him. I did ask her,
8 though. She said she sent Digitek back.

9 Q What --

10 A I don't know.

11 Q What brand of Digoxin did your hospital
12 formulary carry?

13 A Most of them carry Lanoxin.

14 Q No, I'm not asking most of them. I'm asking
15 about the one for which you worked, where you were a
16 pharmacist.

17 A I think it's Lanoxin, but I don't really know.
18 I didn't think to ask that question.

19 Q So you don't know for sure?

20 A No.

21 Q And who was this purchasing person you talked
22 to?

23 A Debbie. You're going to ask me her last name.

24 Q Who does she work for?

25 A Marian Medical Center.

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1 Q Where did she work in 2005, '6, '7, '8?

2 A Marian Medical Center. She's been there for 30
3 years.

4 Q Are you still a member of the Cuesta Society of
5 Hospital Pharmacists?

6 A That is defunct now. So Cuesta Society of
7 Hospital Pharmacists was a subgroup of the California
8 Society of Hospital Pharmacists.

9 Q How many times have you performed an autopsy?

10 A None. I've only been to one.

11 Q How many times have you signed an autopsy?

12 A None.

13 Q How many times have you been consulted by a
14 doctor who was performing an autopsy --

15 A None.

16 Q -- about a cause of death?

17 A None.

18 Q How many times have you signed a death
19 certificate?

20 A None.

21 Q Have you ever made a formal diagnosis of a
22 cause of death in any kind of medical record?

23 A Never.

24 Q Have you ever rendered a diagnosis of a
25 patient's illness in any kind of medical record?

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1 A No.

2 Q Do you consider yourself to be an expert in
3 sudden cardiac death?

4 A No.

5 Q Do you know anything about the rates at which
6 people with Dan McCornack's risk portfolio experience
7 arrhythmias?

8 MR. ERNST: Objection. And for the record,
9 under PTO 22, apparently that's all I'm allowed to do,
10 is say "objection." I can't say why the question is
11 inappropriate. So I just want to clarify when I make an
12 objection, it's for a court to decide later if it's
13 appropriate.

14 THE WITNESS: I did --

15 MR. ERNST: You can go ahead and answer the
16 question after my objection.

17 THE WITNESS: Thank you.

18 I'm not that familiar with it, no.

19 BY MR. MORIARTY:

20 Q The last two pages of Exhibit A are resumes?

21 A That's correct.

22 Q Why do you have two?

23 A Well, a resume is really sort of an
24 advertisement for your services. So when I applied at
25 Marian Medical Center, I didn't think that my primary

1 resume was that much on point, because they didn't
2 really care if I did all of these other jobs. What they
3 wanted to know is whether or not I was a good pharmacist
4 or not, and who they could check and talk to about
5 whether or not I was an appropriate candidate for
6 employment.

7 So I construct one resume for each -- I haven't
8 really used this primary resume for a long time,
9 although I keep updating it, because I haven't applied
10 for any job in a long time. Should I ever want to be a
11 lawyer somewhere else, I'll probably use my primary
12 resume. And if I want to change pharmacy jobs, I'll use
13 the secondary resume. That's the reason.

14 Q When did the Cuesta Society of Hospital
15 Pharmacists become defunct?

16 A About two or three years after I left.

17 Q When did you leave?

18 A Well, I was the president in '91. When I --
19 when I said "left," I meant stopped being an officer in
20 the organization. So about '93, I think.

21 Q So the places, the society has been defunct --
22 okay. Never mind.

23 Are you still a member of the American
24 Association for the Advancement of Science?

25 A Yes.

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1 Q And the California Attorneys for Criminal
2 Justice?

3 A Yes.

4 Q ACLU?

5 A Yes.

6 Q San Luis Obispo County Bar Association?

7 A Yeah. They pronounce it "Lewis," but, yeah.
8 It's sort of like saying Frisco and San Francisco.

9 Q Whatever.

10 Are you still a member of the SLO County Bar
11 Association?

12 A Yes.

13 Q Have you had any teaching positions?

14 A Um, yeah, I taught a course at Cal Poly once.

15 Q What?

16 A It was a business law course. It was not the
17 first-year business law course, which is general
18 business, but it was kind of an eclectic course about
19 everything that wouldn't normally be covered the first
20 year. So I taught sort of nonregulatory agencies and
21 stuff like that.

22 Q Have you ever taught any science courses?

23 A Other than the continuing lectures, or whatever
24 I do as a pharmacist, no.

25 Q Have you published any peer-review articles?

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1 A No.

2 Q Have you presented at national pharmacy
3 conferences?

4 A No.

5 Q Have you presented at statewide pharmacy
6 conferences?

7 A No.

8 Q Have you presented at local pharmacy
9 conferences?

10 A No.

11 Q If there is such a thing?

12 A When I was president of the Cuesta Society I
13 did a couple.

14 Q Were any of your presentations about Digoxin
15 toxicity or postmortem redistribution?

16 A No.

17 Q What is the -- do you have privileges at the
18 hospital?

19 A In the sense of privileges are meant to be a
20 physician, no.

21 Q Okay. Well, Marian Medical Center, what is
22 your --

23 A Designation.

24 Q -- privilege there, or your designation there?

25 A You get two. One is a staff pharmacist, the

1 other is a clinical pharmacist.

2 Q What are you?

3 A Both. At Marian Medical Center we serve both
4 functions. And especially at night when everybody goes
5 home, then all jobs are left to me.

6 Q How often are you called to the floor to
7 consult on a pharmacy issue with a patient?

8 A Do I have to go to the floor to answer that
9 question?

10 The reason I say that is, because my work en --
11 kind of strapped me to my machine, so... But I get
12 questions all night long. So I'm constantly asking
13 questions -- or answering questions.

14 Q Are you telling me --

15 A From either nurses or doctors.

16 Q Are you telling me that you do not go to the
17 floor, but you consult over the telephone on certain
18 things?

19 A Over the last couple years, my getting to the
20 floor has not been very good.

21 Q What is the machine to which you are strapped,
22 so to speak?

23 A Well, what happens is when a doctor writes an
24 order, that order is sent to me and a scan shows up on
25 one of my two screens. And then I review that scan for

1 appropriateness and enter those orders into the computer
2 system. Or if they are not appropriate, then I, you
3 know, call doctors or whoever and try to work that out.
4 It's hard to do at night because I don't want to wake
5 anybody up. But once it gets into the computer system,
6 then that series of events occurs that releases the
7 drawers on the floor for the nurses to get the
8 appropriate drugs at the appropriate time.

9 Q Okay.

10 A Now, I have to keep up with my queue, and so
11 they are constantly coming down. And if I wander off,
12 then my queue will jump real high.

13 Q How many patient beds are there at Marian
14 Medical Center?

15 A Marian Medical Center has just redownsized to
16 80, but they've been running at 120 for the last six
17 months. When I first went there there was about 180.
18 So it's a variable population. But somewhere around
19 100.

20 Q So you're talking about -- it's got at least
21 180 beds, but only about 100 are filled on average?

22 A Yeah.

23 Q Is that what you're saying?

24 A Something happened where we went from a pretty
25 average census of around 160 down to about 100. More

1 healthy population.

2 I have theories on why that is. I think it's a
3 pneumo vac issue, but anyways.

4 Q Do you live in San Luis Obispo County?

5 A Yes, I do.

6 Q So I assume, outside the litigation setting,
7 you've never diagnosed anybody as having Digoxin
8 toxicity while they were alive; correct?

9 A That's correct.

10 Q Outside the litigation setting, you've never
11 rendered a diagnosis that somebody died as a result of
12 Digoxin toxicity?

13 A That's correct.

14 Q And so based on what you've told me before
15 about your prior consulting experience, this is the
16 first and only time that you've rendered a professional
17 opinion about the cause of death; correct?

18 A Other than supporting. So a doctor would call
19 me and say, I have the following symptoms. I think I've
20 got this, that. Is this consistent? I mean that sort
21 of thing I do. I don't know if you call that diagnosing
22 or not. Could be, as far as the specificity of that
23 word.

24 But other than that, no, I don't invite
25 patients to come for the purpose of a diagnosis.

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1 Q Have you ever helped a doctor diagnose his or
2 her patient with Digoxin toxicity?

3 A Never.

4 Q Are you allowed to prescribe drugs?

5 A Well, it depends upon the definition of
6 prescribe. But I do change doses a lot. If that's
7 prescribing, yes. If it's not prescribing, then no.

8 Q Are you able -- I'm sorry.

9 Are you licensed and able under California law
10 to actually prescribe a specific drug?

11 A So --

12 MR. ERNST: Objection.

13 You can go ahead and answer.

14 BY MR. MORIARTY:

15 Q Not a dose change, but prescribe a drug?

16 A Okay. Can I answer this way?

17 MR. ERNST: Object as vague.

18 You can answer the question.

19 THE WITNESS: There are formulary changes that
20 we make. And so let's say a person comes to the
21 hospital and the doctor orders Omeprazole, we don't
22 particularly want to stock that. So I will change it to
23 Protonix. Now, if that's prescribing, yes. If it's not
24 prescribing, then, no.

25 BY MR. MORIARTY:

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1 Q Well, I'm not familiar with those two drugs.

2 A So what I'm doing --

3 Q Is one the generic substitute for the first
4 one?

5 A No, it's a totally changed drug. So I'm
6 changing a drug that's not on the formulary to one that
7 is on the formulary.

8 Q What are those drugs for --

9 A GERD.

10 Q -- the ones you just mentioned?

11 A GERD. They are proton inhibitors, like Nexium.
12 Are you familiar with that? The purple pill? That
13 commercial went around for a while.

14 Q Yeah, I know what they are.

15 A In fact, Omeprazole was originally Nexium.

16 Q When you do those -- when there is a
17 circumstance where there is a formulary change, do you
18 tell the doctor about it?

19 A No, I print out an order and set it up. I look
20 at the profile to make sure it's appropriate. I mean,
21 it's not done in a vacuum.

22 Q Okay. But so far as actually prescribing a
23 drug, other than the circumstances you've described for
24 me, you can't do that?

25 MR. ERNST: Objection.

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1 THE WITNESS: No, I don't invite patients to
2 come to see me for the purpose of treatment.

3 BY MR. MORIARTY:

4 Q Well, whether you invite them or not --

5 A Well, okay. There's no patient comes to me.

6 Q Okay.

7 A I mean, we're not talking about
8 over-the-counter stuff, because people always ask me
9 what to do when they've got a cold. But, yeah.

10 Q I'm talking about prescription medications.

11 A Good.

12 Q Did Mr. Ernst ask you to look at and measure
13 any of the Digitek that he's got in his office of the
14 McCornack family's?

15 A I'm not sure what you mean by that. Did I look
16 at the tablets, yes.

17 Q Do you have a micrometer?

18 A No.

19 Q So you didn't measure any of them?

20 A No, I did not.

21 Q When you -- how long ago did you look at them?

22 A 2009.

23 Q As part of your job --

24 A Can I explain?

25 Q As part of your job --

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1 MR. ERNST: He said can he explain.

2 MR. MORIARTY: What's there to explain? When
3 did you look at them? 2009. What's to explain about
4 that? It's a year. It's a month.

5 MR. ERNST: Objection.

6 BY MR. MORIARTY:

7 Q As part of your job --

8 MR. ERNST: Objection.

9 BY MR. MORIARTY:

10 Q -- do you ever dispense solid oral dose by hand
11 where you're looking at them, counting them?

12 A Not anymore.

13 Q When was the last time you did that?

14 A When I worked at Community Health Centers,
15 which is on my resume.

16 Q So when you looked at the McCornack tablets --

17 MR. ERNST: He's referring to -- he's going to
18 give you that.

19 THE WITNESS: Do you want that date?

20 MR. MORIARTY: No, he told me where it was. I
21 can look it up.

22 MR. ERNST: You asked him when it was, and he
23 was looking. If you want the answer, he will give you
24 the answer.

25 BY MR. MORIARTY:

1 Q When you looked at the McCornack tablets, what
2 did you do?

3 A I tried to identify them by the numbers and
4 shapes and sizes, make sure that they were Digitek
5 product. I think the question was initially, you know,
6 did Mr. McCornack get Digitek as opposed to some other
7 version of Digoxin. And is this an appropriate case to
8 bring, was the initial question.

9 And so my recollection is, although it's very
10 faint now, 2009, I identified those as -- with a pill
11 identifier. You know, there's lots of programs and
12 books that you can use to tell which product you have.

13 Q Do you believe you did that before this lawsuit
14 was filed?

15 A I don't know if it was before or after.

16 Q Okay. So what else did you do other than
17 identify them as Digitek?

18 A That's all I did.

19 Q Well, did you look at them --

20 A Oh, yeah.

21 Q -- for uniformity of size, shape --

22 A No.

23 Q -- color?

24 A Not really.

25 Q At that point did you know that the drug had

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1 been recalled?

2 A I think it was just starting to happen, but I
3 don't -- it's hard for me to recollect exactly. I don't
4 remember.

5 Q Well, according to that bill you showed me
6 before, the initial consult was in August of 2009?

7 A Correct.

8 Q The recall had happened a year and a quarter
9 before that.

10 A Okay.

11 Q Did you know at the time --

12 A I might not have known. But -- and I might
13 have known. I don't -- I can't really recall.

14 Q Well, if you did know --

15 A I would be lying if I told you an answer.

16 Q -- did you know what the FDA-approved recall
17 notice said about the purpose of the recall?

18 A Well, when Mr. Ernst asked me to consult on
19 this case, I did go and look on the internet to see if
20 Dig had been recalled. I saw the FDA, but I didn't -- I
21 don't remember if I read the whole notice, but I read
22 some of it.

23 Q Did you ever look on the FDA's website to see
24 what they said about Digitek?

25 A I don't remember if I did or not.

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1 Q Okay. This is MDL Exhibit 38. It's from the
2 FDA's website called "The Facts and Myths about Generic
3 Drugs."

4 Have you ever seen this before?

5 A No, I have not.

6 Q I want you to go to the second page.

7 First myth says, "There are quality problems
8 with generic drug manufacturing. A recent recall of
9 generic Digoxin, paren, called Digitek, close paren,
10 shows the generic drugs put patients at risk."

11 Do you see that?

12 A I do.

13 Q Did I read it correctly?

14 A You read it correctly.

15 Q All right. In the first bullet point --

16 MR. ERNST: What's the date of this?

17 MR. MORIARTY: It was first posted in July of
18 2009. Before he was consulted.

19 MR. ERNST: Is this on --

20 MS. AHERN: It's on the website.

21 MR. ERNST: Pardon me?

22 MS. AHERN: You can still find that on the
23 website.

24 MR. ERNST: But is there a date on this
25 document?

1 MR. MORIARTY: Not on this one.

2 THE WITNESS: Nope, that was --

3 THE REPORTER: I'm sorry, what did you say?

4 THE WITNESS: I was mumbling.

5 BY MR. MORIARTY:

6 Q There is no date other than the date we printed
7 this.

8 A Right.

9 MS. AHERN: If you go to the actual website it
10 will have a date that it was first posted.

11 MR. ERNST: Did you print the website date?

12 MR. MORIARTY: No. This was printed June 15th,
13 2010, the week before I went to depose your
14 pharmaceutical experts in New Jersey and elsewhere.
15 This was posted in July of 2009. Okay?

16 MR. ERNST: And you know it was posted in July
17 of 2009 because of?

18 MR. MORIARTY: Because I've looked at this
19 repeatedly on the FDA's website. Okay.

20 MR. ERNST: I'd like to take a short break.

21 MR. MORIARTY: Well, wait a minute. I need to
22 ask him about this.

23 MR. ERNST: I'd like to take a short break.

24 MR. MORIARTY: Okay.

25 (Recess.)

1 BY MR. MORIARTY:

2 Q So, Mr. Gibson, I was in the middle of
3 questioning you about Exhibit 38. Did you talk to
4 Mr. Ernst at all about Exhibit 38 on the break?

5 A Did we talk? I don't think we did.

6 Q You can't ask him.

7 A I'm sorry. I don't -- not exactly, no, I don't
8 think we did.

9 I think we talked about -- well, I posed the
10 question, I'm not quite sure why you're asking me the
11 stuff you're asking me. I don't know what the context
12 of this is. So I'm kind of confused.

13 We talked about whether or not --

14 MR. ERNST: There's no question pending.

15 MR. MORIARTY: Yes, I did. I asked him what
16 did you talk about?

17 MR. ERNST: No, you asked him if you talked
18 about Exhibit 38.

19 BY MR. MORIARTY:

20 Q So what did you talk about?

21 A I might be in error exactly when our first
22 initial consultations might have been. Unfortunately, I
23 don't do this regularly, so I don't keep real good
24 records about --

25 Q All I'm asking is what you talked about in the

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1 hall --

2 A That's what we talked about.

3 Q -- in the middle of my questioning about an
4 exhibit.

5 A That's what we talked about.

6 Q Let's get back to Exhibit 38, and I wanted to
7 ask you about the first bullet point. It starts to talk
8 about a March 2008 FDA inspection. Do you see that?

9 A Uh-huh.

10 Q It says, "Included in this list of products was
11 one particular lot of Digitek." Do you see that?

12 MR. ERNST: Thank you.

13 BY MR. MORIARTY:

14 Q Do you see that?

15 A I do.

16 Q And then it says, "Actavis detected a very
17 small number of oversized tablets in this lot,
18 specifically 20 double-sized tablets in a sample of
19 approximately 4.8 million tablets."

20 Do you see that?

21 A I see that.

22 Q Did I read it correctly?

23 A You read it correctly.

24 Q The third bullet talks about the Actavis
25 attempts to remove the tablets and GMP and things like

1 that; correct?

2 A Correct.

3 Q All right. Go to the fourth bullet point.

4 A One, two, three, four. "Since the detection"?

5 Q Yes. Second sentence. "In our best judgment,
6 given the very small number of defective tablets that
7 may have reached the market and the lack of reported
8 adverse events before the recall, harm to patients was
9 very unlikely."

10 Did I read that correctly?

11 A Yes.

12 Q Do you have any reason to disagree with the
13 Food and Drug Administration's web statement about this
14 topic?

15 A I think -- yes.

16 Q You do?

17 A Yeah.

18 Q Tell me about it.

19 A Well, this is something that I from the very
20 beginning, whenever you have tablets sticking to a
21 press, one can look at that as a mechanical problem,
22 which I think is the way Actavis has looked at it. Has
23 to do with dyes and stuff like that.

24 But another way of looking at it is that it
25 might be a part of the formulary variabilities that were

1 occurring within the product. The formulary
2 variabilities is sort of the crux of the issue here, in
3 that if there were formulary -- formulation
4 variabilities, that that would change bioavailability --
5 changes in bioavailability would change the Digoxin
6 levels.

7 So when tablets stick to a press, is that a
8 symptom or is that -- I mean, it could be a symptom of a
9 greater problem.

10 Q Who said that tablets were sticking to a press?

11 A I read that somewhere in something I reviewed.

12 Q Well, actually, have you read any FDA documents
13 in this case?

14 A I've read what Mr. Ernst has provided me.

15 Q Well, does that include 483s and warning
16 letters?

17 A I don't think so.

18 Q Does it include -- did he send you any batch
19 records from the manufacturing process?

20 A No.

21 Q Have you read the depositions of Mr. Bliesner,
22 Soma, Kenney, or Farley?

23 A No. But I did review --

24 Q Okay.

25 MR. ERNST: He --

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1 THE WITNESS: Just to be accurate, I did
2 review -- yes, I did review this from Bliesner.

3 BY MR. MORIARTY:

4 Q That's his report?

5 A Okay. That's his report.

6 Q You didn't review his deposition.

7 A Okay.

8 Q Right.

9 MR. ERNST: Well, you're making a statement.
10 He's reviewed --

11 BY MR. MORIARTY:

12 Q Did you review David Bliesner's deposition?

13 A I'll answer your question. Yes -- no, I did
14 not.

15 Q Thank you. That's all I'm asking you.

16 So what I'm asking you, though, is not whether
17 you think this is a formulary issue. I'm asking whether
18 you have some basis to disagree with the specific
19 statement that I read from the FDA's website.

20 MR. ERNST: Objection.

21 THE WITNESS: Am I supposed to accept the FDA
22 as -- I don't accept the FDA as all-knowing. I mean, I
23 read this just now. It's what it is. I don't know if
24 it's true. I don't know if it's not true.

25 BY MR. MORIARTY:

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1 Q Well, do you think that --

2 A I don't think that it is true.

3 Q Do you think that the FDA knows the difference
4 between a formulary issue and a --

5 A Yes.

6 Q -- manufacturing problem?

7 A I don't -- I don't want to pass judgment on the
8 FDA on whether or not they'd be giving out patient
9 information to calm fears. I don't know if they lied or
10 didn't tell the truth in this. I don't know. It's
11 beyond my --

12 Q I'm asking you --

13 MR. ERNST: He needs to finish answering his
14 question.

15 MR. MORIARTY: Go on.

16 MR. ERNST: You're continually interrupting
17 him.

18 THE WITNESS: I'm just saying it's just beyond
19 my purview to judge this document.

20 BY MR. MORIARTY:

21 Q So you have no basis to agree or disagree;
22 correct?

23 MR. ERNST: Objection; misstates his testimony.

24 THE WITNESS: Prior to today I've never read
25 it.

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1 BY MR. MORIARTY:

2 Q Okay. Mr. Gibson, you're here as a science
3 witness, not a lawyer.

4 A Correct. I understand that.

5 Q Do you have some scientific basis today to
6 agree or not agree?

7 A I don't particularly agree with it, no.

8 Q What's your scientific basis for not agreeing
9 with this statement by the FDA?

10 A When we were in pharmacy school, there were a
11 small group of drugs that we were cautioned never to
12 substitute generic for the innovated product, and Dig
13 was one of them. And the reason that was true was
14 because changes in formulation can make changes in
15 bioavailability, which can change Dig levels.

16 And so it has always, since the first time I
17 saw a Digitek tablet, been a question in my mind, should
18 we be doing this? Should anybody be doing this? Can
19 you assure me that this Digitek product has the same
20 exact same bioavailability innovated product. So that's
21 the questions that I have.

22 Now, the difference in cost is not that great.
23 I don't understand why people were substituting.
24 Whether or not this document is written for -- to calm
25 the populous or whether it's politically motivated, I

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1 don't know. There's no footnotes. It's just not my
2 kind of thing to look at.

3 Q Okay. That's fine. If it's not your kind of
4 thing to look at, you just tell me that.

5 You got your pharmacy degree in 1980; is that
6 correct?

7 A That's correct.

8 Q Have you ever read anything about the history
9 of bioavailability of Digoxin products since that time?

10 A Periodically.

11 Q Have you read the bioavailability study for
12 Digitek?

13 A No.

14 Q Did you know there was a bioavailability study?

15 A I absolutely assumed there was a
16 bioavailability study done.

17 Q As part of their ANDA?

18 A That's correct.

19 Q So you have no reason to question the
20 availability of Digitek, in general, against Lanoxin, do
21 you?

22 MR. ERNST: Objection.

23 THE WITNESS: Well, you're making -- that
24 question makes the assumption that the production
25 techniques used for the tablets that were tested were

1 exactly the same as the production techniques used for
2 the tablet that was distributed.

3 BY MR. MORIARTY:

4 Q But you have not seen manufacturing records,
5 quality assurance records, any records from my client's
6 company; correct?

7 A Except for Mr. Bliesner's reports.

8 Q He's a plaintiff's expert.

9 You haven't seen the records; correct?

10 A That's correct. You are absolutely correct.

11 Q What pharmacy publications do you subscribe to
12 or read on a regular basis?

13 A On a regular basis, you know, there's what we
14 call throw-aways. I look at all of those. I'm -- I get
15 a ton of mail.

16 You know what I mean by throw-aways?

17 Q Yes.

18 A Pharmacy Times, Drug topics, those sort of
19 things.

20 In the pharmacy, we have -- we have -- well,
21 when I was at General we regularly got the Medical
22 Letter and the Pharmacist's Letter.

23 I generally don't review peer-review articles
24 unless something drives me to try to solve a problem.

25 Q Okay. Do you keep any toxicology texts in the

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1 lab or the pharmacy department --

2 A Yes.

3 Q -- at your hospital?

4 Which ones?

5 A This is a truncated version of the one that we
6 have in the pharmacy.

7 Q Gerald Leikin's book?

8 A Leikin and Paloucek, yes.

9 Q Do you have any others?

10 A I have others in my library. We regularly --

11 Q Such as?

12 A I have "Medical Toxicology."

13 Do you want me to pull all of my books out?

14 Q The one you just put on the table is by
15 Ellenkohm and Barceloux. B-a-r-c-e-l-o-u-x; correct?

16 A Yes.

17 Q You have a Goodman and Gilman's there?

18 A I have Goodman and Gilman. I keep a copy of
19 the Washington manual. I have Evans and Schentag's book
20 on Pharmacokinetics. Here's a very ancient text that I
21 like a lot. Then, of course, I keep the Merck manual.
22 And this is just from my private library.

23 Q This one is called --

24 MR. ERNST: He's --

25 MR. MORIARTY: He's put a bunch of books on the

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1 table. Can I read the title of one so we can keep this
2 straight?

3 MR. ERNST: Yes, but he --

4 BY MR. MORIARTY:

5 Q Textbook of Biopharmaceutics and Clinical
6 Pharmacokinetics by N-i-z-a-i; correct?

7 A Correct.

8 Every one of these represents a footnote in my
9 report.

10 Q Okay.

11 A Can I put them away?

12 Q Yes.

13 A Thank you.

14 Q Have you ever ordered a serum Digoxin
15 concentration level on a patient?

16 A We do that for patients in hospitals. It's one
17 of the new Jayco recommendations for patients' safety.
18 If a person is on Dig, when he enters the hospital, the
19 pharmacists are required to order Dig levels for them.

20 Q When was that put in?

21 A I can't tell you that exactly. I know I've
22 been mandated by my employer to do so and so I do.

23 Q How many times have you done it?

24 A I work at nights. It's not that common.

25 Most -- I don't get that many admits that are -- that

1 have Dig at night.

2 Q Have you ever, on your own discretion, ordered
3 a serum Digoxin concentration level on a patient?

4 A Yes. Whenever I'm entering drugs and I see
5 abnormalities, like a high serum creatin, and I know
6 there's a person on Dig, I've done that.

7 Q So you, at your hospital, have the authority as
8 a pharmacist to order lab studies?

9 A Some, yeah.

10 Q Okay.

11 A Can I make this perfectly clear? The majority
12 of it is done by the clinical pharmacist who works the
13 eight-to-whatever shift.

14 Q Have you ever worked in a lab that tested
15 pharmaceutical products?

16 A No.

17 Q Do you have any military service?

18 A Three months and seven days. I was a cadet at
19 the United States Air Force Academy.

20 Q Did you voluntarily withdraw from that
21 institution?

22 A I did.

23 Q Outside the litigation setting, how often do
24 you review full medical records?

25 A In my current job, I have for the last five

1 years. When I worked at General Hospital, um, I was --
2 I did some QA that involved reviewing full medical
3 records.

4 Q Okay. So how many times do you think you've
5 done that in your career?

6 A Oh, it comes up periodically. So, geez, I
7 wouldn't know. Not -- it's not that often. Ten, 15
8 maybe.

9 I mean, usually what happens is you show up
10 with -- in the old days before it was all electronic,
11 you'd show up with medical records, and there would be a
12 large stack of medical records, and you would do what
13 you needed to do as part of the QA and pass them along.

14 Q Now, in this -- I'm going to ask you some
15 questions about your report, which is Exhibit A.

16 A Sure.

17 Q You can use this version or --

18 A I have a copy.

19 Q -- or your version.

20 Do you need a copy, Don?

21 MR. ERNST: I'm fine. Sure. I'll take that.

22 No reason to waste paper.

23 BY MR. MORIARTY:

24 Q In this collection of footnotes, there are a
25 number of articles specifically about Digoxin?

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1 A That's correct.

2 Q And postmortem redistribution of Digoxin.

3 Okay?

4 A Uh-huh.

5 Q How many of those had you read before you were
6 consulted as a part of this litigation?

7 A None.

8 Q All right. So I assume that you footnoted the
9 items that you did here because you were relying on them
10 for the various propositions that you talk about in this
11 report; correct?

12 A That is one of two reasons I did it.

13 The other one is, is my method of note taking,
14 and I do that so that I can, you know, between the time
15 you write the report and some other time you become cold
16 on a topic, and this way I can pull up the material. If
17 I have a question as to where the -- I might have got
18 something, I have a footnote that directs me.

19 Q Sure. But you put them in here because you
20 considered them to be reasonably reliable pieces of
21 authority for whatever proposition you were citing them
22 for?

23 A Correct.

24 Q Now, getting back to this first paragraph, one
25 of your charges was to provide an opinion about the

1 postmortem drug levels for Mr. McCornack's blood?

2 A Correct.

3 Q How many times in a nonlitigation setting have
4 you been asked to render opinions about postmortem drug
5 levels?

6 A This is a novel event for me.

7 Q First time?

8 A Yes.

9 Q So, obviously, this is the first time you've
10 been ever asked to look at postmortem Digoxin levels?

11 A Correct.

12 Q In a nonlitigation setting have you ever been
13 asked to render opinions about the distribution of
14 Digoxin and other drugs postmortem?

15 A Not postmortem, no.

16 Q Before this piece of litigation, have you ever
17 been asked to render opinions about the effect of
18 different formulations of Digoxin on bioavailability?

19 A It has been a continuing discussion that occurs
20 regularly, yes.

21 I mean, pharmacists are capable, or do
22 substitute generic drugs. And so there are continuing
23 discussions about whether or not you're going to bring
24 this into a pharmacy or not.

25 I mean, my opinion has always been not to, but

1 I'm an old-fashioned-type guy. Because in 1980, I mean,
2 we were severely warned, and I believe it still to be
3 true, that changes in variation in formulation can be --
4 have disastrous effects.

5 Q Do you know whether FDA ever cited or warned
6 Actavis about changes in formulation of Digitek --

7 A The only time --

8 Q -- between 2005 and 2008?

9 A The only things I know is in the report by
10 Dr. Bliesner. I don't have it memorized every bit
11 that's in here. But that's what I know.

12 Q So you don't independently know --

13 A That's correct.

14 Q -- anything about that?

15 Do you know whether FDA ever cited or warned
16 Actavis about changes in bioavailability at any point
17 regarding Digitek?

18 A I don't know if they did or not.

19 Q So let me get back to my question.

20 Have you ever rendered a professional opinion
21 that is documented anywhere about the effect of
22 differing formulations of Digoxin on bioavailability?

23 A No.

24 Q Go to the second page of your report, please.

25 A Sure.

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1 Q Second full paragraph.

2 A Yes.

3 Q At the end you're talking about when
4 Mr. McCornack consumed his medications?

5 A Correct.

6 Q Do you see that?

7 A Yes.

8 Q It does make a big difference -- well, let me
9 step back.

10 If a doctor was going to draw a serum Digoxin
11 concentration on Mr. McCornack at approximately
12 midnight, would you agree that it would be very
13 important to know whether he took his last dose at
14 6 p.m. or 8 p.m.?

15 MR. ERNST: Objection.

16 THE WITNESS: Well, peaks are generally drawn
17 anywhere from four to six. And so it's not that
18 specific. I mean, it is a number. It's just a number.

19 You do -- you do generally discuss peaks,
20 though. You don't discuss troughs.

21 BY MR. MORIARTY:

22 Q What do you mean, peaks are drawn at four to
23 six?

24 A Well, for instance, if I wanted to find out
25 what your Digoxin level is, I need to do so in a

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1 consistent part of the time curve so that I can
2 constantly be referencing that consistent part of the
3 time curve.

4 The generally accepted idea is to draw it at
5 the peak time, which is somewhere between four to six
6 hours after the administration of the dose.

7 Q Where do you get that? What's the cite for
8 that proposition?

9 A Everywhere. I mean every textbook. They all
10 say that.

11 Q Don't they say six to eight?

12 A Well, what did I reference?

13 Q Yeah, I'm not asking about a peak. I'm
14 asking -- this is a very specific question.

15 A Correct.

16 Q If somebody was going to draw a serum Digoxin
17 concentration on Mr. McCornack at midnight, would it be
18 important to know whether he took his last dose at
19 6 p.m.?

20 A Or 8 p.m.

21 Q Or 8 p.m.?

22 A It could be.

23 Q Okay. What does the FDA-approved product label
24 say about the optimal time to draw serum level?

25 A That I don't know.

1 Q When you are going to draw serum levels as part
2 of clinical practice, are you looking for the peak or
3 are you looking for steady state?

4 MR. ERNST: Objection; compound.

5 THE WITNESS: Actually, that doesn't really
6 make sense, the question.

7 Um, the peaks will be consistent at steady
8 state. Steady state is defined as the time in which the
9 intake of the drugs sort of equal the outtake of the
10 drugs. So steady state defines five to seven times. A
11 halflife, you're about 90 percent of steady state. At
12 steady state, the peaks will be consistent, and that's
13 what you're looking for.

14 BY MR. MORIARTY:

15 Q Okay.

16 A So you don't want to --

17 Q So it's your understanding that clinicians draw
18 serum levels in order to look for peaks?

19 A Uh-huh.

20 Q Okay. Do you have a citation at that?

21 A No, not right off the top of my head.

22 I can tell you, though, that Digoxin is one of
23 those drugs in which there are pharmaceutical protocols
24 in which doctors ask us to dose their drugs, and in
25 every pharmacy protocol I've worked under that involve

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1 Digoxin peaks were desired as a reference point because
2 they are the most consistent.

3 Q Okay.

4 A Easy to obtain.

5 Q Let's go after your first little chart here.

6 A So the first little chart?

7 Q Wait a minute. Actually, let's stick with the
8 chart.

9 A Okay.

10 Q That's his last serum level; correct?

11 A That I could find.

12 Q Okay. Do you know what time he took his dose
13 that day?

14 A I do not know exactly.

15 Q Well, if Mr. McCornack typically took his dose
16 at breakfast and dinner --

17 A Then he would have taken it at the time this
18 level was drawn.

19 Q Yeah. Too close in time to the dose; right?

20 A Right.

21 Q But we don't know whether he skipped his
22 morning dose because he was going to the doctor; right?

23 A We don't know that.

24 Can I say, though, that it appears to me to be
25 a nadir or a trough more than a peak. And I assume that

1 he didn't wake up at four in the morning to take his
2 dose. So this is more the kind of level that, if I was
3 doing the protocol, I would want redone.

4 Q Well, if -- I know this involves a lot of
5 variables, but if a patient's trough level is 1.6, what
6 do you expect his daily peak would be?

7 A Well, it depends a lot on those other
8 variables. So it's hard for me to say.

9 You know, I thought about trying to calculate
10 that before I came today, but I did not get around to
11 doing that. So I --

12 Q After the first chart, there's a little
13 paragraph about postmortem drug levels were obtained.
14 Do you see that?

15 A Yes.

16 Q Then it says those levels were obtained from a
17 peripheral site. Do you see that?

18 A That's correct.

19 Q What's the basis for that statement?

20 A The testimony or the deposition of the -- I
21 believe it comes from the deposition of the --

22 Q Coroner.

23 A -- coroner. Thank you.

24 Q Do you independently know whether the axillary
25 vein is considered central or peripheral?

1 MR. ERNST: Objection.

2 THE WITNESS: I'm not too sure those words
3 have that specific a meaning. So, no.

4 BY MR. MORIARTY:

5 Q Do you have any opinion to a reasonable degree
6 of scientific probability where the trace level of
7 quinidine came from in Dan McCornack's postmortem blood?

8 MR. ERNST: Objection.

9 THE WITNESS: Total puzzle. It could be
10 something he drank that day.

11 BY MR. MORIARTY:

12 Q All I asked is whether you had an opinion --

13 A I do not.

14 Q -- to a reasonable probability.

15 Okay. Let's go to the next page, at the top.
16 It says, "The distribution of the Digoxin is minimal to
17 body fat. High concentrations to myocardium, skeletal
18 muscles and kidney."

19 Do you see that?

20 A Uh-huh.

21 Q Name several of the skeletal muscles to which
22 there would be high concentrations distributed.

23 A Well, skeletal muscles are like biceps,
24 triceps, thigh muscles, calves. I mean, those are all
25 skeletal muscles. Skeletal muscles differ from

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1 myocardial muscle.

2 Q I understand that. I just asked you to name a
3 couple.

4 Pectoral muscles?

5 A Pectoral muscles.

6 Q Okay. Let's go to -- you have this citation to
7 G-L-O-B-A-L R-P-H?

8 A What page? I'm sorry.

9 Q The next page after where we were. Sorry.
10 Page 4.

11 A Global RPH.

12 Q Yes.

13 A That's a website. I didn't -- given the time
14 constraints in writing this report, I didn't do these
15 calculations by hand, so I used Global RPH.

16 Are you familiar with that website?

17 MR. ERNST: Did we mark the report yet as an
18 attachment to this deposition? "A." Thank you.

19 And is there anything else that's been marked
20 other than this?

21 MR. MORIARTY: Yes, the notice is "B."

22 MR. ERNST: Okay.

23 (Defendants' Exhibit C was marked for
24 identification.)

25 BY MR. MORIARTY:

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1 Q This I'm not going to mark yet completely, but
2 the first part that I'm holding in my right hand is
3 marked C. Do you see that?

4 A I see that.

5 Q Is what I'm holding in both hands part of the
6 Global RPH website?

7 A I believe it is.

8 MR. ERNST: Do you have a copy of that for me?

9 MR. MORIARTY: I have a copy of this part. I
10 don't think I have a copy of the second part. But I'll
11 get it.

12 THE WITNESS: The first part, if I could
13 describe it, the first part is the calculator, Digoxin
14 dosage calculator, which I used as trying to demonstrate
15 the difference in steady levels with the change of
16 bioavailability.

17 The second, I believe, is a description of
18 calculations in which the program engaged in.

19 BY MR. MORIARTY:

20 Q Let me ask about this. In the Digoxin
21 calculator, which is Gibson Exhibit C --

22 A Uh-huh.

23 Q -- and there's all kinds of advertising around
24 the peripheral --

25 A Yes, it is.

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1 Q -- of this; correct?

2 A Yes.

3 Q And then on the second page, if you go to that,
4 there's a disclaimer. Do you see that?

5 A Yes.

6 Q And it says, "The authors make no claims of the
7 accuracy of the information contained herein. And these
8 suggested doses are not a substitute for clinical
9 judgment."

10 A That's correct.

11 Q Did I read that correctly?

12 A That is correct.

13 Q Have you ever used this website before this
14 litigation setting?

15 A Oh, yes.

16 Q Do you know the extent to which doctors use
17 this website in making any sort of dosing decisions?

18 A I don't think they do. I don't know, though.

19 Q Do you know the people who are behind this
20 website?

21 A No.

22 Q Do you know anything about their
23 qualifications?

24 A They've been around for a long time. Um, they
25 seem to have quoted all of the appropriate documents. I

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1 assumed they did the calculations correctly. I did not
2 hand out calculations myself.

3 Q Okay.

4 A You know what I mean. I did not do the
5 calculations myself.

6 Q And I assume that this is -- obviously, this is
7 designed for dosing calculations on living patients;
8 right?

9 A That's correct.

10 Q Okay.

11 A Do you want that back? I'll get it.

12 MR. MORIARTY: Do you want the second page of
13 that? You can have mine.

14 MR. ERNST: I want to make sure they are both
15 marked as Exhibit C.

16 MR. MORIARTY: I'm going to clip them together
17 or have her clip them together.

18 MR. ERNST: Thank you.

19 BY MR. MORIARTY:

20 Q Have you ever specifically used this site
21 before this case for any Digoxin calculations?

22 A Yes.

23 Q And that was in -- was that in assisting some
24 doctor in making dosing decisions?

25 A Yes.

1 Q Do you have any opinion to a reasonable
2 scientific probability about the bioavailability of the
3 tablets that Mr. McCornack was taking prior to his
4 death? Digitek tablets?

5 MR. MORIARTY: Objection. The standard.

6 You can go ahead and answer the question.

7 THE WITNESS: Do I know what the
8 bioavailability is? You're asking for very specific
9 things all morning. So the question --

10 BY MR. MORIARTY:

11 Q Let me withdraw the question that I asked. I
12 want to ask it a different way.

13 Do you have an opinion to a reasonable
14 scientific probability whether the bioavailability of
15 Mr. McCornack's tablets was any different from the
16 FDA-approved formula for Digitek?

17 MR. ERNST: Objection.

18 THE WITNESS: So, I kind of didn't see my role
19 as to go into that part of it, so I didn't -- I just --
20 part of my report makes the assumption that if Mr. Ernst
21 can prove that there's formulation issues, is it
22 possible that those formulation issues can result in a
23 toxic dose of Digoxin. That was my point here.

24 BY MR. MORIARTY:

25 Q Okay. But just so I'm clear, when I walk out

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1 of here --

2 A Right.

3 Q -- I need to know, you don't today currently
4 have an opinion to a reasonable scientific probability
5 about whether his tablets did or did not deviate from
6 the FDA approval?

7 A I have not tested them nor followed through on
8 that.

9 Q Thank you.

10 Let's go to the next page. The first sentence
11 says, "Life-threatening arrhythmias are the most
12 important toxic effect of Digoxin."

13 Do you see that?

14 A Yes.

15 Q Do you know whether life-threatening
16 arrhythmias are the most common toxic side effect of
17 Digoxin?

18 A Well, that's a difficult issue, and I don't
19 think anybody knows whether it's the most common or not.
20 There has been some discussion about nausea and vomiting
21 being one of the most common issue with Digitoxicity.
22 I'm not quite so sure this -- I think there are a number
23 of people who can be Dig toxic and not be -- not have
24 nausea and vomiting. They show up with other
25 arrhythmias.

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1 There's always the comorbid disease states,
2 they can confuse the clinical pictures. So is the
3 nausea and vomiting because they have other illnesses?

4 So the answer to your question is, I don't
5 know -- I don't know if anybody knows.

6 Q Okay. So then you've got this chart here,
7 which comes from Goodman and Gilman?

8 A Correct.

9 Q Right?

10 A Yes.

11 Q Now --

12 A Now, it comes from the 11th edition.

13 Q Correct.

14 Does Goodman and Gilman provide citations for
15 this?

16 A I assume they do.

17 Q Can you find them for me, please?

18 A Are you ready? Tell me when you're ready.

19 MR. ERNST: Just read them into the record.

20 THE WITNESS: Read them into the record?

21 MR. ERNST: Sure.

22 MR. MORIARTY: No, I want to see them.

23 MR. ERNST: Well, that's fine.

24 THE WITNESS: Okay. This is a copy of this
25 section of Goodman and Gilman.

1 BY MR. MORIARTY:

2 Q Okay.

3 A It's the front page. Then I don't know what
4 you would call this page. I looked at this page to find
5 out.

6 Q All I need is the cite.

7 A And you'll notice right there, there's little
8 numbers that I cited and here's the references here.

9 Q So your reading of this is that the Meridian
10 paper in Clinical Pharmacokinetics in 1988, and the
11 Smith and Hobber paper in the Journal of Clinical
12 Investigations in 1970 are the sources for these --

13 A Numbers.

14 Q -- numbers?

15 A Correct.

16 Q Have you read those papers?

17 A Have not.

18 Q And certainly -- you can take that back.

19 A Okay.

20 Q Certainly, the Digoxin concentration that is
21 listed in the left side of your chart here on Page 5 is
22 a serum level taken from a living patient?

23 A Correct.

24 Q So do you have any independent information
25 about the degree to which other peer-reviewed medical

1 articles support these percentages?

2 MR. ERNST: Objection.

3 THE WITNESS: Well, the problem with Goodman
4 and Gilman -- and they are probably the most respected
5 textbook in the field. I would imagine it's been more
6 than anybody could be vetted. I couldn't imagine that
7 they would make an error.

8 You know, and the point is not to play the
9 numbers exactly. They are just trying to demonstrate a
10 point. And the point being, that as you rise in the
11 serum Dig level, the probability of having an arrhythmia
12 arises and they're giving a demonstration.

13 So at 1.7 your chances are 10 percent. 2.5.
14 But that's not an exact number. It's just a patient
15 population they study, and they are just trying to
16 demonstrate this concept.

17 Q Okay. Do you know in any of the papers that
18 support these numbers what the percentages was -- what
19 the percentage were of fatal arrhythmias?

20 A You know, not exactly. But you know, people
21 have interesting new charts that --

22 Q So in the papers --

23 MR. ERNST: Would you just --

24 MR. MORIARTY: No, because he's going to a
25 different paper and he's not answering my question.

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1 MR. ERNST: He --

2 MR. MORIARTY: I will give him a chance to
3 answer this, Don.

4 MR. ERNST: You are continually interrupting
5 him.

6 MR. MORIARTY: I am not.

7 MR. ERNST: You are interrupting his answers
8 when you don't like what he has to say.

9 BY MR. MORIARTY:

10 Q I'm going to ask you a simple question and then
11 you can explain it in this paper.

12 MR. ERNST: He was not done answering the last
13 question. What you want you to do is limit his answers.
14 This --

15 MR. MORIARTY: Fine. I'll move to strike his
16 last answer as nonresponsive.

17 MR. ERNST: And I would ask --

18 BY MR. MORIARTY:

19 Q I'm going to ask you answer this --

20 MR. ERNST: Let's read it again. Let's read
21 the question again.

22 BY MR. MORIARTY:

23 Q I'm going to ask you this question: Do you
24 know in the two papers cited in Goodman and Gilman that
25 form the basis of this chart, how many of these were for

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1 fatal arrhythmias?

2 A I do not know.

3 Q Okay. Now, do you believe that the Leiken
4 paper that you brought with you today --

5 A Which --

6 Q -- answers that question?

7 A I don't know. I just got it last night. I
8 have not had an opportunity to study it.

9 But I didn't put this document -- this stuff in
10 there to absolutely prove the truth of the assertion so
11 much as to show the concept that the rise in a serum Dig
12 level can cause a rise in the propensity for
13 arrhythmias.

14 Q Okay.

15 A That's all I was trying to do.

16 How many of those are fatal -- or not fatal, I
17 mean, is Mr. McCornack the 10 percent? 90 percent do
18 not have fatal. I mean, I don't know that exactly.
19 It's just another data point to consider when looking at
20 the clinical picture of Mr. McCornack's demise.

21 Q Thank you.

22 Now, after the chart, you talk about noncardiac
23 symptoms; correct?

24 A Yes.

25 Q Did he have any of the ones that you describe

1 here the day or night of March 22nd, 2008?

2 A I did not find a reference to any of those.

3 Now, I reviewed the deposition of his wife. I
4 did not review the deposition, although I was given it
5 just recently, I haven't had time to study that, of the
6 two boys.

7 And I did not find that he had nausea and
8 vomiting or visual disturbances, or what's the other
9 one?

10 Q Okay. Now, underneath that, you are talking
11 about the factors influencing the likelihood of toxicity
12 from the Goodman and Gilman text; correct?

13 A Correct. I use that as sort of a framework for
14 my discussion in the paper.

15 Q Right.

16 A So what are the possibilities that might cause
17 an abnormally high Dig level.

18 Q All right. So let's look at number 3. Can you
19 rule out to a certainty that Mr. McCornack accidentally
20 took too many Digitek at some point in the days leading
21 to his death?

22 MR. ERNST: Objection.

23 THE WITNESS: I considered that and thought
24 about it a lot. That's why I have a paragraph about his
25 use of a pill dispenser.

1 And the reason, because I was concerned, not a
2 question that you had here, but with the alcohol use he
3 might have miscalculated the number of tablets. So I
4 was trying to see if there was any particular evidence
5 that would make it look like he might have taken an
6 incorrect number of tablets. All I have is that he used
7 a pill dispenser, and it's somewhat inconsistent to
8 think that with a pill dispenser you would take an
9 incorrect number of tablets.

10 Q So, in your opinion, it is unlikely; correct?

11 A Yeah.

12 Q But you can't rule it out to a certainty?

13 A To a reasonable doubt, no.

14 Q Now, number 6 talks about -- or I'm sorry,
15 number 5, decrease in renal function; correct?

16 A Correct.

17 Q Now, renal function can be measured in lab
18 tests; right?

19 A Yeah. Estimations.

20 Q Estimations?

21 A It's incorrect to say you can measure. The
22 only way you can really measure it is to do a 24-hour
23 urine collection. It can be estimated.

24 Q To the best of your knowledge, no lab studies
25 have been taken to check his renal function since

1 months, maybe almost a year --

2 A Almost a year.

3 Q -- before his death?

4 A That's right, yeah.

5 Q So do you have any scientific data available

6 which allows you to rule out the possibility of

7 number 5, a decrease in renal function in this case?

8 A Well, there was no evidence that he had any
9 symptoms of. So based on that, I ruled it out.

10 Q My question was, did you have any scientific
11 data, lab data? Do you have any --

12 A Okay. You want lab data. No, I don't have any
13 lab data.

14 Q Electrolyte abnormalities are typically
15 assessed using laboratory data?

16 A That's absolutely correct.

17 Q So number 6, do you have any lab data to rule
18 out the possibility that Mr. McCornack had electrolyte
19 abnormalities?

20 A I don't have any lab data from that.

21 Q Okay. And number 8 is other pharmacological
22 agents; correct?

23 A Correct.

24 Q And we know that Mr. McCornack was taking
25 Diltiazem; correct?

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1 A Correct.

2 Q Have you read the FDA-approved product label
3 for Diltiazem?

4 A I'm afraid I haven't.

5 Q You've read something about Diltiazem --

6 A I've read about Diltiazem at length.

7 Q In your many books?

8 A Correct.

9 Q Okay.

10 A And I've cited --

11 Q Mr. Gibson -- Mr. Ernst keeps telling me that
12 I'm interrupting you. You do have to wait for me to
13 finish my question.

14 A I thought you asked me --

15 MR. ERNST: He wasn't finished with his answer.

16 THE WITNESS: I just didn't want to be
17 inaccurate.

18 MR. MORIARTY: Don, it's always my fault.

19 THE WITNESS: I just didn't want to be
20 inaccurate. That's all. You asked me if I reviewed any
21 documents, and I have the -- amongst all of my textbooks
22 and stuff, I also reviewed the one that I cited, the
23 consensus.

24 BY MR. MORIARTY:

25 Q I'm well aware of that. You've read about

1 Diltiazem. You've cited it here. I ask one question at
2 time.

3 One had to do with the label.

4 A Right.

5 Q Then the books. But you've read about
6 Diltiazem; right?

7 A I'm sorry, books, articles, they all kind of
8 fuzz in my mind being the same sort of reading.

9 Q Do you know, based on your reading, that
10 Diltiazem has the risk of arrhythmias?

11 A Yes.

12 Q Have you done any reading that indicates to you
13 the risk of arrhythmias at increased Diltiazem levels?

14 A Yes.

15 Q Okay.

16 A Have I -- you asked me have I read, right?

17 Q Yes.

18 A Yes.

19 Q Now, on page 5 of your report, you have this
20 little chart about the risk of arrhythmias at higher
21 Digoxin levels. Do you have a little chart for the
22 Diltiazem?

23 A I could not find, in my literature research,
24 any correlations that made any sense that I thought I
25 could cite.

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1 Q Okay. So you don't know what the increased
2 risk of arrhythmia, if any, is with a 25-percent
3 increase in the Diltiazem level?

4 A That's correct.

5 Q Over therapeutic?

6 A That's correct. I don't know if anybody knows
7 a numerical correlation between the vitreous and
8 Diltiazem level. Most of them are very confusing
9 whether Diltiazem level should or shouldn't be.

10 Q Let's go to page 6 of your report.

11 A Okay.

12 Q At the end of your bullet points you've got the
13 maximum dose of Diltiazem as 540 milligrams per day?

14 A Correct.

15 Q Based on what you said on the first page of
16 your report, Mr. McCornack was on the maximum daily dose
17 of Diltiazem, was he not?

18 A He was.

19 Q Was he also -- withdraw that.

20 Two paragraphs down, you're talking about the
21 question of whether we can determine the level of
22 Digoxin in the blood at the time of death arises in this
23 case.

24 Do you see that sentence?

25 A Yes.

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1 Q And then you talk about hair?

2 A Right.

3 Q There was no hair sample in this case, was
4 there?

5 A No.

6 Q Dr. Mason did not draw any vitreous sample, did
7 he?

8 A Not that I know of.

9 Q From your reading in the area to prepare for
10 your opinions in this case, you did see that vitreous
11 was a type of sample that could be drawn for comparison;
12 right?

13 A It could be drawn.

14 Q Right.

15 A Its value, I have a different opinion about. I
16 don't know if it's that valuable.

17 Q I'm asking you whether it's another data point.

18 A It is another data point.

19 Q You know that Dr. Mason only drew one blood
20 sample; correct?

21 A That I know about.

22 Q So down a couple paragraphs from that, you're
23 talking about postmortem redistribution refers to one
24 subset of those changes; correct?

25 A Correct.

1 Q You cite the Koren article; is that right?

2 A I believe so.

3 Q Okay. Do you have your copy of the Koren
4 article there?

5 A I hope so. It will take me something to find
6 it, but --

7 Q It's Koren and MacLeod, 1985. Journal of
8 Forensic Sciences; correct?

9 A That's the rat study, yes.

10 MR. MORIARTY: That can be "D."

11 (Defendants' Exhibit D was marked for
12 identification.)

13 BY MR. MORIARTY:

14 Q That is the study that you cite in footnote 34
15 on page 6; correct?

16 A That's correct.

17 Q All right. I want to ask you a couple
18 questions about this.

19 This -- in the abstract, a couple sentences
20 from the end, it says, "Therefore antemortem Digoxin
21 intoxication cannot be reliably inferred on the basis of
22 high postmortem levels of the drug."

23 Did I read that correctly?

24 A You read that correctly.

25 Q Do you agree with that?

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1 A Not totally.

2 Q Let's go to the discussion section at page 94
3 of the article.

4 A Can I use this one?

5 Q Sure. The first sentence says, "In common with
6 earlier reported human studies, the first part of our
7 experiment indicates that in the rat, low antemortem
8 serum levels during life tend to increase significantly
9 after death."

10 Did I read it correctly?

11 A You read it correctly.

12 Q Do you agree with it?

13 A I agree with it.

14 Q And one of the articles to which they refer to
15 is the Vorpahl and Coe article?

16 A Correct. Yes. I guess I should look before I
17 say yes. I assume that's what I did. Yeah.

18 Q And page 95 of this article --

19 MR. ERNST: Did you finish reading that
20 paragraph?

21 MR. MORIARTY: I'm sorry, he answered the
22 question I asked him. If you want to ask him about it
23 later, you can.

24 MR. ERNST: Well, if you only read part of the
25 paragraph.

1 MR. MORIARTY: I asked him about a sentence.

2 Q Let's go to page 95.

3 MR. ERNST: But I would just ask him to read
4 the second sentence.

5 BY MR. MORIARTY:

6 Q You don't have to do that because it's in my
7 part of the examination.

8 A Sure.

9 Q When he gets to his part, he can do what he
10 wants.

11 MR. ERNST: Not that he doesn't have to, he can
12 to make it clear so it's at one location of the
13 deposition.

14 BY MR. MORIARTY:

15 Q First full sentence, "After death it appears
16 that cessation of the active modulating accumulation
17 process takes place, and as a result Digoxin is
18 redistributed passively from tissues containing Digoxin
19 in high concentration into areas of lower concentration
20 such as the blood."

21 Did I read it correctly?

22 MR. ERNST: Objection.

23 THE WITNESS: I believe -- I believe you read
24 it correctly.

25 BY MR. MORIARTY:

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1 Q Do you agree with it?

2 A I do.

3 MR. ERNST: Objection.

4 BY MR. MORIARTY:

5 Q Then at the -- towards the bottom, in sort of a
6 conclusion section, they say, "Our findings have several
7 implications for the interpretation of postmortem
8 Digoxin levels in serum as well as various tissue."

9 A Uh-huh.

10 Q Number two in that section says, "Antemortem
11 Digoxin intoxication cannot be reliably inferred on the
12 basis of high postmortem levels of the drug alone."

13 MR. ERNST: Objection.

14 BY MR. MORIARTY:

15 Q Did I read it correctly?

16 A Can I have a moment to read it, please.

17 MR. ERNST: Sure.

18 THE WITNESS: Is the bullet point 1? No.

19 BY MR. MORIARTY:

20 Q Two.

21 A Two, I'm sorry. You've read it correctly.

22 Q Do you agree with it?

23 A Well, in total, if you are assuming that
24 sentence means it cannot be used for any purpose, then I
25 disagree.

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1 Q Okay.

2 A If you are saying that I can extrapolate
3 backwards with a certain precision, then I agree.

4 Q Okay. So down further in your report on page
5 6 --

6 A Do you want this back?

7 Q -- you say, Digoxin was identified by these
8 authors as a candidate for PMR?

9 A Correct.

10 Q And you're citing the Yarema and Becker
11 article; correct?

12 A Correct.

13 Q Do you have Yarema and Becker in your material?

14 A I may have, but just the abstract of that. I
15 don't think I copied the whole. I have so much stuff
16 here, I didn't put it in order of -- I thought of
17 putting it in order of the cite so I can -- but my time
18 restraints prohibited me from -- I believe I do have the
19 abstract. I don't know if I have the full article.

20 Q Okay. Well, let me read you from the abstract.

21 A Sure.

22 Q And ask you whether you agree with this
23 statement.

24 MR. ERNST: And --

25 MR. MORIARTY: Unfortunately, I only brought

1 one copy of this one. I thought he'd have it.

2 MR. ERNST: Well, stand by.

3 MR. MORIARTY: Okay.

4 MR. ERNST: Can I review what you're going to
5 ask him, please?

6 MR. MORIARTY: Well, I'm going to read him a
7 statement and ask him if he agrees with it. Then you
8 can read the article if you want.

9 THE WITNESS: Here's the article.

10 BY MR. MORIARTY:

11 Q Do you have the article?

12 A I do.

13 Q Okay. Could you move it a little closer to
14 Mr. Ernst so he can follow along.

15 A Sure, be happy to.

16 Q If he wants to.

17 At the end of the abstract, it says, "Medical
18 toxicologists participating in forensic cases involving
19 drugs likely to undergo PMR must be aware of its
20 potential contribution to the postmortem drug
21 concentration. Correlation with laboratory data and any
22 available antemortem or perimortem clinical information
23 is necessary to render an appropriate opinion on the
24 cause of death."

25 Did I read that correctly?

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1 A I believe you did.

2 Q Do you agree with that?

3 A Absolutely.

4 Q Let's go to page 237.

5 Is Digoxin listed as one of the drugs known to
6 undergo PMR?

7 A In this article?

8 Q Yes.

9 MR. ERNST: Where are you?

10 MR. MORIARTY: Page 237, left column.

11 THE WITNESS: It says, "Examples of drugs known
12 to undergo PMR," and they have tricyclic antidepressants
13 and then the second one is Dig.

14 BY MR. MORIARTY:

15 Q Okay. So let's go to page 238. There's a
16 section called sampling location. Do you see that?

17 A I do.

18 Q It says, "Peripheral blood is less likely to be
19 subject to the postmortem elevations in drug
20 concentrations seen in central blood sources such as the
21 heart."

22 A Absolutely.

23 Q Do you agree with that?

24 A I agree.

25 Q And it says "less likely." It doesn't say

1 there is no PMR in peripheral specimens, does it?

2 A No, you're right. There is PMR in peripheral
3 samples. It depends on concentration in time because
4 it's a passive event.

5 Q So on the second column, where it says time of
6 sampling, after the cite to article 55, it says, "As
7 previously discussed, the variation in time from death
8 to blood sampling may account for the differences
9 between studies and concentrations of morphine and other
10 drugs." Right?

11 A Sure.

12 Q I'm done asking you about Yarema and Becker.

13 A Thank you.

14 Q Page 7 of your report, you refer to Ferner, do
15 you not?

16 A I do.

17 Q And when you refer to Ferner, you are referring
18 to this article?

19 A I don't know if you have it in color, but it's
20 got a blue square at the top, from the British Journal
21 of Pharmacol.

22 MR. MORIARTY: Exhibit E.

23 (Defendants' Exhibit E was marked for
24 identification.)

25 MR. ERNST: Thank you.

1 BY MR. MORIARTY:

2 Q I'm going to ask you about this.

3 Okay. Do you have it in front of you?

4 A I do.

5 Q In the abstract, the second sentence says,
6 "Postmortem changes render the assumptions of clinical
7 pharmacology largely invalid, and make the
8 interpretation of concentrations measured in postmortem
9 samples difficult or impossible."

10 MR. ERNST: Objection.

11 BY MR. MORIARTY:

12 Q Did I read it correctly?

13 A You read it correctly.

14 Q Do you agree?

15 A To an extent.

16 Q Okay.

17 A Not totally.

18 Q What do you disagree with that?

19 A Well, there are things you can say about
20 postmortem drug level that is high. For instance, you
21 can say they did take Digoxin. You can also say he has
22 substantial store of Digoxin. You can also say there
23 was a concentration gradient enough to make it want to
24 spread in that direction. Because you're really going
25 from high concentration to low concentrations in a very

1 passive sort of way.

2 Sometimes I think that is even more damaging to
3 say that in a peripheral sample you have a very high Dig
4 concentration, because that means -- not damaging. It's
5 more probative that what you're looking at is a very
6 high Dig score. Dig scores correlate somewhat with Dig
7 levels at the time of demise. So you can't totally
8 discount the Dig level that's postmortem. But you
9 can't -- I don't know if you can extrapolate backwards.
10 You know, you remember geometry, it takes two points to
11 make a line. I don't have any way to make a slope. Can
12 I with any measurable amount of accuracy extrapolate
13 backwards? Probably not. But I can make certain
14 statements about the patient's capacity to have Dig
15 aboard that would do this distribution.

16 Q Okay. Let's go to page 433.

17 A 433.

18 Q Of Exhibit E.

19 A 432, 433, got it.

20 Q Left column.

21 A Left column.

22 Q First full paragraph is talking about for most
23 fatalities.

24 A Yes.

25 Q "For most fatalities assumptions of steady

1 state before death are invalid. So that greater
2 allowance needs to be made for variability within and
3 between subjects."

4 Do you agree with that?

5 A Partially.

6 Q Okay. Further down, it says, "After death, and
7 in the most favorable circumstances, it is possible to
8 take samples of whole blood flowing from femoral veins.
9 This sample is thought to be least susceptible to
10 postmortem change."

11 Do you see that?

12 A Yes.

13 Q Do you agree with that?

14 A The greater the distance from the heart, the
15 less likely it's going to be to exhibit postmortem
16 distribution, yes.

17 Now, your question assumes femoral vein. I
18 mean, it stems all of the way from the hip on down. So
19 I mean what part do you draw from?

20 But the distance from the heart, based on this
21 passive redistribution, it's going to be less the
22 farther down.

23 Q Where was Mr. McCornack's sample drawn from?

24 A Well, I read the deposition, and it sounded
25 like -- I can't remember right off the top of my head.

1 But I assumed it to be somewhat peripheral. The exact
2 location I didn't think was all that important, so I
3 didn't spend much time thinking about it.

4 Q Well, if the farther from the heart the
5 least -- the less PMR there's going to be, wouldn't it
6 be important to know which vessel was accessed so you
7 would know?

8 A Well, yes, in some ways you're right. I should
9 have probably pursued that. But he had an extreme -- he
10 had a really high Dig level, which meant there was a
11 good storage of Digoxin on board.

12 And I agreed completely with his statement back
13 here that you can't always assume that they're in steady
14 state. I think he was in a steady state and that there
15 was a change that was causing his Dig levels to rise.

16 Q What do you mean, he had a high store of
17 Digoxin or a really high Dig level?

18 A Well, the 3.2 is a high level.

19 Q Well, it was 3.6.

20 A I'm sorry, 3.6 is a high Dig level to have.

21 Q At your hospital, do you have any knowledge of
22 inpatients who have a 3.6, whether the cardiologist or
23 internist would even order Digibind?

24 A They would.

25 Q How do you know that?

1 A They do. I've observed it.

2 Q Just based on the 3.6, or is it based on
3 something else?

4 A Well, the problem with Dig in a lot of people's
5 minds is, you know, you can't play with numbers. So
6 it's really a clinical picture. There are, on record,
7 people that have extremely high Dig levels who don't
8 seem to have any adverse effects, or not a lot of stated
9 toxicity.

10 It in some ways depends on how long they've
11 been on the Dig. If you've been on the Dig for a long
12 period of time, there's -- there's a greater propensity
13 to lock that drug up into -- into the third compartment,
14 if you will. That may be a little inaccurate
15 pharmacokinetic reference, if you will.

16 But the heart is going to take up the Dig. So
17 that level is more probative of what -- if he's a
18 chronic user. If it's just a suicide attempt, that
19 level is not so indicative of what might be in the
20 heart, because the longer you take the drug, the more
21 absorption, the more reuptake the heart will take, the
22 larger the scores will be.

23 Q Are you done with your answer?

24 A Yes.

25 Q You said something about you just can't play by

1 the numbers. I assume by that you mean in trying to
2 figure out whether the patient is toxic, you're trying
3 to look at all data available, optimally an EKG,
4 history, serum level?

5 A If you have one.

6 Q BUN, creatine, GFR?

7 A If you have all that stuff, it's optimal.

8 Q Yeah, optimally.

9 A Yeah, optimally.

10 Q So I think what you're saying is you don't make
11 a diagnosis of toxicity based on a number alone;
12 correct?

13 MR. ERNST: Objection.

14 THE WITNESS: In some ways, what you are saying
15 is absolutely true, although a 3.2 would make me --

16 MR. MORIARTY: 3.6.

17 THE WITNESS: 3.6 --

18 Why do I keep saying 3.2? I'm sorry. I
19 apologize.

20 -- would make me seriously consider how much
21 Dig storage was on board.

22 MR. MORIARTY: Okay.

23 MR. ERNST: We've been going another hour, if
24 we can take a break.

25 MR. MORIARTY: Let me just finish this article

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1 and then we can.

2 MR. ERNST: That's fine.

3 BY MR. MORIARTY:

4 Q Let's just go to the conclusion of the Ferner
5 article.

6 A Sure.

7 Q Skip all of the stuff in between. Are you
8 there?

9 A I am there.

10 Q It says, "There is no reliable or obvious
11 connection between concentrations measured in life and
12 subsequent to death."

13 A I see that.

14 Q "Consequently, concentrations measured after
15 death cannot generally be interpreted to yield
16 concentrations present before death."

17 Do you agree with that?

18 MR. ERNST: Objection.

19 THE WITNESS: I do not agree with that.

20 BY MR. MORIARTY:

21 Q Why?

22 A Well, because you can't just discount a data
23 point. He had a level of Dig that was 3.6 at the time
24 of death. That's a significant number. You can't just
25 say, well, because you can't reliably extrapolate

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1 backwards, that I have to totally discard my data. Do
2 you see what I'm saying? It's not the same sort of
3 analysis.

4 What he's trying to say here is that you can't
5 really extrapolate backwards and determine exactly what
6 the Dig level was at the time of death. And I agree
7 with that. There's too many other variables. You don't
8 know how fast the passive distribution went. You don't
9 have measures of that sort of thing. But you do know
10 that this patient took a substantial amount of Dig to
11 even get a PMR of 3.2.

12 BY MR. MORIARTY:

13 Q 3.6?

14 A Six.

15 Q Every time you say 3.2, I'm asking the court
16 reporter to put in 3.6.

17 A Please. I'm so sorry.

18 Q I assume you've never independently run
19 experiments on PMR of Digoxin or any other drug?

20 A You assume correctly.

21 Q Okay.

22 MR. MORIARTY: Take that break now.

23 (Recess.)

24 BY MR. MORIARTY:

25 Q We are plodding through your report, and we are

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1 on page 7.

2 A Okay. I'm there.

3 Q I want you to go to the second paragraph after
4 your indented Ferner quote.

5 It says, "Digoxin may exhibit a passive
6 redistribution after death."

7 Do you see that statement?

8 A I do.

9 Q In paper after paper that you've read, hasn't
10 that been proven to be the case?

11 A I believe it to be true.

12 Q And it's the consensus in the scientific
13 community that Digoxin can passively redistribute after
14 death?

15 A Some redistribution does occur after death.

16 Q The next sentence says, "It has been suggested
17 that the ideal site," those words being in quote, "to
18 obtain blood is a ligated or clamped femoral vein."

19 Do you see that?

20 A Yes.

21 Q And why ligated?

22 A I think they meant, you know, so it would be
23 separated physically from any blood that may come down
24 from the heart in a passive redistribution way.

25 Q So, for example, in a femoral vein you would be

1 concerned that blood would come down from the heart
2 through --

3 A Other veins.

4 Q -- other veins to that site?

5 A Yes.

6 Q Correct. So, in an axillary vein, for example,
7 the concern would be that you would be getting
8 subclavian or even heart blood; right?

9 MR. ERNST: Objection.

10 THE WITNESS: So I agreed with that rather
11 quickly. I do want to make the point that it is a
12 matter of distance from the heart to the site which you
13 collect blood. Even though it could be very proximal to
14 the heart, it might not be -- it may be as close as the
15 crow flies, but close in terms of veins. So that's a
16 point that needs to be made. The farther you are away
17 from the heart, the more ideal the site would be.

18 BY MR. MORIARTY:

19 Q Well, isn't it also a matter of the size of the
20 specimen?

21 A Well, they tend to test very small portions of
22 the specimen nowadays. I mean, I don't know what you
23 mean by that.

24 Q Well, if you draw enough blood from a femoral
25 vein that is nonligated, eventually you're going to get

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1 blood from somewhere --

2 A That's correct.

3 Q -- other than a femoral vein; correct?

4 A That's absolutely correct.

5 Q Again, in the last sentence of the last
6 paragraph on page 7, you're talking about femoral vein
7 is less than redistribution into central vessels;
8 correct?

9 A Correct.

10 Q Less, not none; right?

11 A Oh, yeah.

12 Q Now, on this page, you've got cites to two
13 other articles. Number 43 is the, I call it French
14 paper. It's Pelissier-Alicot; right?

15 A Uh-huh. Yeah, I just threw that in there as
16 another example of redistribution acknowledged in the
17 literature.

18 Q And that article is what I'm marking as
19 Exhibit F; correct? You have this in your binder?

20 (Defendants' Exhibit F was marked for
21 identification.)

22 THE WITNESS: I don't know if I do or not.

23 BY MR. MORIARTY:

24 Q Well, if you don't, you can use the version --

25 A Thank you.

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1 Q -- I have right there. But it is footnote 43
2 to your --

3 A Yes.

4 Q -- report; correct?

5 A Correct.

6 Q So the first sentence in the abstract of that
7 article says, "Postmortem drug concentrations do not
8 necessarily reflect concentrations at the time of death
9 as drug levels may vary according to the sampling site
10 and the interval between death and specimen collection."

11 Do you agree with that?

12 A Yes.

13 Q And is that the consensus in the scientific
14 community?

15 A Well, it's a consensus that it's going to flow
16 from high concentration to low concentration, and it's a
17 passive redistribution, which means that it's an osmotic
18 type of effect, that, you know, it's not going to flow
19 in a postmortem way to the femoral veins if that's going
20 up in concentration gradient. So it has to go down in
21 concentration.

22 Q But it's also a consensus of the scientific
23 community that sampling site and the interval between
24 death and specimen collection are important?

25 MR. ERNST: Objection.

1 BY MR. MORIARTY:

2 Q Right?

3 A Yes.

4 Q In other words, time matters?

5 A Time matters.

6 Q In all of the scientific papers that you read
7 to prepare for your opinion in this case, did you make
8 note of the longest time period between death and
9 sampling?

10 A No. I didn't think it was all that relevant.

11 Q How long was it between Mr. McCornack's death
12 and when his blood was sampled?

13 A Right off the top of my head, I can't remember.

14 Q Would you agree that it was between 75 and 80
15 hours?

16 A Something like that. I don't remember exactly.

17 Q Does that exceed the longest postmortem draw
18 interval that you've seen in the literature by a
19 magnitude of at least three times?

20 A I didn't pay attention to that particular
21 aspect, because I didn't think that that sort of
22 extrapolation was the best method to get at this
23 underlying question that I was asked.

24 Q But if time matters, why didn't you account for
25 time?

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1 A Time matters to the level, but that level
2 doesn't necessarily -- I can't extrapolate from that
3 level back to the time of his death with any accuracy.
4 I don't care what time it is. Thirty hours, 25 hours.
5 You know, if you did it contemporaneous with death,
6 maybe.

7 MR. ERNST: You're talking about the specific
8 level?

9 THE WITNESS: Right, a specific level.

10 BY MR. MORIARTY:

11 Q Okay.

12 A But there are definitely things you can say
13 about the postmortem level. So I didn't follow through
14 to examine that issue.

15 Q Let's go to page 541 of this Exhibit F. On the
16 left side, this section called "Practical Consequences
17 in Forensic Toxicology"?

18 A Right.

19 Q Before I ask you about that, you're not a
20 toxicologist; correct?

21 A I don't know what you mean by "toxicology."
22 Toxicologist. There is no profession --

23 Q Do you have a degree in toxicology?

24 MR. ERNST: You've interrupted him.

25 MR. MORIARTY: Fine, finish.

1 MR. ERNST: Let him finish his answer.

2 BY MR. MORIARTY:

3 Q Go on.

4 A I am a pharmacist. I've had training in
5 toxicology, yes. Pharmacology, toxicology is an issue
6 that we deal with at work, yes. I mean, you can't do
7 pharmacology without worrying about toxicology. It's
8 not a fine line to separate it.

9 Q Do you have a degree in toxicology?

10 A I have a degree in pharmacy.

11 Q That's not what I asked. It's about as simple
12 a question I can ask.

13 MR. ERNST: Objection.

14 BY MR. MORIARTY:

15 Q Do you have --

16 MR. ERNST: Argumentative.

17 BY MR. MORIARTY:

18 Q -- a degree in toxicology?

19 A I don't even know what degree that would be.
20 I'm sorry.

21 Q Okay.

22 A You could have --

23 Q Can you have a Ph.D. in toxicology?

24 MR. ERNST: Objection. You've interrupted him
25 again.

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1 BY MR. MORIARTY:

2 Q Can you have a degree in toxicology?

3 MR. ERNST: Objection. You've interrupted him
4 again.

5 MR. MORIARTY: Why are you interrupting me?

6 MR. ERNST: Because you won't let him finish
7 answering the question.

8 BY MR. MORIARTY:

9 Q Finish answering my question.

10 A I don't even know where we are. I'm sorry.
11 What was the question?

12 Q Can you have a Ph.D. in toxicology?

13 A You can have a Ph.D., and you can have a Ph.D.
14 in a department that calls itself either pharmacology or
15 toxicology. They are all very much the same, in that
16 it's the topic matter may change some. A lot of the
17 departments that deal in toxicology tend to deal with
18 environmental toxins or industrial toxins. Pharmacology
19 is the study of pharmaceutical toxins, if you will. Dig
20 is a well-known toxic agent.

21 Q Do you even bill yourself as a toxicological
22 consultant?

23 A I never thought that toxicology can be
24 separated from the issue.

25 Q Okay. Is there anything in your C.V. about a

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1 degree in toxicology, a Ph.D. in toxicology, or a board
2 certification in toxicology?

3 A Okay, no.

4 Q So let me ask you about this. Second sentence
5 in this section.

6 MR. ERNST: Where are you reading?

7 BY MR. MORIARTY:

8 Q "Practical consequences in forensic
9 toxicology."

10 MR. ERNST: This is --

11 BY MR. MORIARTY:

12 Q In Exhibit F, the French article.

13 "It is very important in postmortem testing to
14 be able to compare concentrations in several blood and
15 tissue samples, even if reference values for drug
16 concentrations in tissues are often missing."

17 Do you agree with that?

18 MR. ERNST: Objection.

19 THE WITNESS: If you have the time and the
20 ability, sure, I guess.

21 BY MR. MORIARTY:

22 Q Is there anything that you can see from
23 Dr. Mason's autopsy process that indicated he had
24 neither the time nor the ability to draw vitreous sample
25 or a second blood sample?

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1 A I can't answer that question --

2 MR. ERNST: Objection.

3 THE WITNESS: -- for you.

4 BY MR. MORIARTY:

5 Q Second paragraph in that section, "As for the
6 peripheral blood sampling sites, all the authors
7 recommend collecting blood from the femoral vein.
8 Femoral blood appears to be the specimen of choice for
9 postmortem toxicological analysis as it is the least
10 subject PMR, which in this case can only come from the
11 local tissues such as muscles and fat."

12 Do you agree with that?

13 MR. ERNST: Objection.

14 THE WITNESS: It's fairly accurate, yeah.

15 BY MR. MORIARTY:

16 Q Okay.

17 A It's just a data point, though. I don't know
18 what you're getting to. I'm missing the point. I'm
19 sorry.

20 Q Mr. Gibson, I'm not here to make points. I'm
21 here to ask you questions about the points you've made.
22 Okay?

23 A Okay.

24 Q Just so we're clear on the process.

25 MR. ERNST: Objection. Move to strike.

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1 BY MR. MORIARTY:

2 Q Also, on page 7 of your report, your footnote
3 of the Cook and Braithwaite article. It's number 45 in
4 your citations; correct?

5 A Uh-huh.

6 MR. MORIARTY: I only have one extra of these.
7 Do you have --

8 MR. ERNST: Did you mark this?

9 BY MR. MORIARTY:

10 Q Do you have a copy of --

11 A Can I see?

12 Q -- of your Cook and Braithwaite from your
13 binder?

14 A I don't know.

15 Q So you have your binder copy so Mr. Ernst can
16 look at the --

17 Don, I brought an extra. Sorry, I didn't think
18 I had it.

19 MR. ERNST: Thank you.

20 BY MR. MORIARTY:

21 Q Okay. I want to ask you some questions about
22 this.

23 A Okay.

24 Q Now, by the way, I've been asking you about
25 these articles.

1 Now, earlier I asked you sort of a broad
2 question about how many of these you had in your library
3 and had read before this consultation in this case, and
4 I think your answer was none; correct? Of the articles?

5 MR. ERNST: Well, I'm going to object.

6 THE WITNESS: I have these that I have here.

7 BY MR. MORIARTY:

8 Q Okay.

9 A I don't understand your question.

10 Q I guess I'll just have to get specific.

11 A Ask your question again.

12 Q The French article, Exhibit F --

13 A I have it.

14 Q -- did you have this article and you had read
15 it before you were consulted in this case?

16 A I don't know if I had that article. I've read
17 it.

18 Q Before you were consulted in this case?

19 A Oh, I'm sorry, before. No. I did not have it
20 before.

21 Q Cook and Braithwaite, had you read this before
22 you were consulted?

23 A No, I have not.

24 Q What about Yarema and Becker or Ferner?

25 A I have not read any of them. I'm sorry, I

1 misunderstood your question. The preface was before I
2 was asked to consult in this case. I had not read these
3 articles.

4 Q So Cook and Braithwaite -- I don't know what I
5 just did with my copy of it.

6 A There's this copy.

7 Q Here it is. Let's go to the conclusion in the
8 abstract.

9 A Okay.

10 Q "A large degree of error can arise from
11 attempting to estimate antemortem drug concentrations in
12 the ingested dose from postmortem measurement"?

13 MR. ERNST: Objection.

14 MR. MORIARTY: Why do you keep interrupting me?

15 Q "The chosen site and technique for postmortem
16 blood sampling can greatly influence the concentration
17 of drug measured."

18 Do you agree with that statement?

19 MR. ERNST: Objection.

20 THE WITNESS: To a degree, yes.

21 BY MR. MORIARTY:

22 Q Okay. Okay. In the second column, the first
23 full paragraph, it says, "Often pathologists or
24 toxicologists are requested to estimate the amount of
25 drug present at the time of death or the number of

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1 tablets consumed. This assumes that the drug
2 concentration found at postmortem examination is a
3 reliable estimate of that present at the time of death.
4 There's a lack of evidence such an extrapolation is
5 possible."

6 Do you agree with that statement?

7 MR. ERNST: Objection. That doesn't finish the
8 sentence.

9 BY MR. MORIARTY:

10 Q Do you agree with what I've read so far?

11 MR. ERNST: Objection.

12 THE WITNESS: I'm kind of fatigued, but --
13 generally, but not -- if you are implying that you can't
14 get anything out of the level, then I would disagree
15 with it.

16 BY MR. MORIARTY:

17 Q Okay.

18 A But his wording is very explicit here,
19 extrapolation. I don't think you can extrapolate.

20 Q Okay.

21 A You can do some extrapolation, though. I don't
22 think he means that.

23 Q The remainder of the sentence is, "In only a
24 few cases reported in the literature are antemortem
25 blood concentrations available for comparison with

1 values from a variety of sites at postmortem exam."

2 Do you see that?

3 A Yes.

4 Q Now, in this case we do not have an antemortem
5 comparative, do we?

6 MR. ERNST: Objection.

7 THE WITNESS: No.

8 MR. MORIARTY: What could you possibly object
9 to that for? Unless you have an antemortem blood level
10 that I don't know about.

11 MR. ERNST: Well, under --

12 THE WITNESS: The assumption that --

13 MR. MORIARTY: Go on. Never mind.

14 MR. ERNST: No, he gets to answer the question.

15 MR. MORIARTY: My question wasn't to him. It
16 was a lawyer by-play.

17 THE WITNESS: I know.

18 BY MR. MORIARTY:

19 Q Do you have something to add to your previous
20 answer?

21 A Yes, your assumption was do we have an
22 immediate antemortem that's contemporaneous with his
23 death, and we don't.

24 Q We don't have one for ten months, do we?

25 A For ten months, though. We do have that one.

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1 (Defendants' Exhibit G was marked for
2 identification.)

3 BY MR. MORIARTY:

4 Q Let's go to 284 of Exhibit G. Are you there?

5 A I am.

6 Q Last full paragraph in the left column, "It is
7 often necessary to determine whether the drug
8 concentration found at postmortem examination should be
9 attributed to either therapeutic ingestion or overdose.
10 This is very difficult to determine because of the
11 influences of postmortem change."

12 Do you agree with that so far?

13 MR. ERNST: Objection.

14 THE WITNESS: It can be.

15 BY MR. MORIARTY:

16 Q "The use of PM/AM ratios or back extrapolation
17 from a postmortem concentration is not recommended."

18 Do you agree with that?

19 A If you're asking for precision, that's right.

20 Q The last full paragraph of this article starts
21 with, "Our study shows that a high degree of error can
22 arise from attempting to predict antemortem
23 concentrations from postmortem concentrations and
24 emphasizes the need for continued research into this
25 area of pathology practice. The absence of such data,

1 estimates of circulating drug concentrations during life
2 should not be made."

3 Do you agree with that?

4 MR. ERNST: Objection.

5 THE WITNESS: With precision, that's correct.

6 BY MR. MORIARTY:

7 Q Okay. In your work on the science part of your
8 professions --

9 A Yes.

10 Q -- the pharmacy part of your profession, is
11 precision important?

12 A It is.

13 Q So, for example, if the question about whether
14 somebody died of a drug overdose or not is an important
15 and serious issue, isn't it?

16 A It is very.

17 Q So, for example, in a criminal case -- and you
18 handle criminal cases as a lawyer -- it's very important
19 for your client and possibly your client's liberty
20 whether it was a drug -- the person who died died of a
21 drug overdose that supposedly your client gave them --

22 A Uh-huh.

23 Q -- or for just some other reason; right?

24 A Right.

25 MR. ERNST: Objection. Objection. Move to

1 strike.

2 BY MR. MORIARTY:

3 Q If you were the lawyer in a case like that
4 where the question in the trial was whether your client
5 had committed murder or whether the person had died of a
6 heart attack, you would want some scientific precision
7 from the prosecuting experts, wouldn't you?

8 MR. ERNST: Objection. Multiple objections.
9 Under PTO 22 I can't state. I'm not supposed to state
10 it, but...

11 THE WITNESS: You know, if I was a lawyer, yes,
12 I would want to get as precise a picture as possible.

13 BY MR. MORIARTY:

14 Q If you have been sued in a pharmaceutical case
15 as opposed to a legal malpractice case like you have
16 been recently, you would want the opposing expert to be
17 scientific and precise, wouldn't you?

18 MR. ERNST: Objection. Multiple objections.

19 THE WITNESS: Do you want me to answer that?

20 BY MR. MORIARTY:

21 Q Yes.

22 A Okay. Sure.

23 I have no idea.

24 Q Let's go to page 8 of your report.

25 A Okay.

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1 Q You're referring to the Vorpahl and Coe
2 article; correct?

3 A Somewhere in there I'm sure I did.

4 Q At the top, first line.

5 A Okay.

6 (Defendants' Exhibit H was marked for
7 identification.)

8 MR. ERNST: You marked this as?

9 MR. MORIARTY: "H."

10 Q You can either use the version in your binder
11 or you can use what I've just put in front of you as
12 Exhibit H.

13 A Thank you.

14 Q What was the longest postmortem interval in the
15 Vorpahl and Coe?

16 A Do you want me to look it up?

17 Q Well, I know it was 22-point some odd hours,
18 but if you want to look it up, go ahead.

19 A Okay. 22-point some odd hours.

20 Q Okay. So let's go to the discussion section on
21 page 333.

22 A Got it.

23 Q First sentence, "It is clear from this
24 investigation that postmortem Digoxin levels taken from
25 cardiac blood, venous blood or vitreous humor do not

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1 mirror the antemortem levels. Substantial increases in
2 serum levels occur following death irrespective of the
3 source of the sample."

4 First of all, do you agree with Vorpahl and Coe
5 that that's what they found in their investigation?

6 MR. ERNST: Objection.

7 THE WITNESS: That's a more complicated
8 question.

9 You did read it correctly, if you want to ask
10 that question.

11 BY MR. MORIARTY:

12 Q I'm not asking whether you agree with it,
13 because what they are saying here is they are commenting
14 on their own investigation.

15 A Right, they are. And they are saying it's
16 clear that postmortem Dig levels taken from cardiac
17 blood, venous blood, vitreous humor do not mirror the
18 antemortem levels.

19 When you say "mirror," I interpret that to mean
20 that there's some linear relationship or correlation
21 that can be ascertained.

22 Q Or that they are the same?

23 A Or that they are the same, right.

24 Q Okay. Well, do you agree that that's at least
25 what they found?

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1 A That's their conclusion.

2 Q Okay. And this paper is cited in many of the
3 other papers that you read; correct?

4 A Probably every one of them.

5 Q Well, do you agree with -- do you agree that
6 their finding has been consistently reaffirmed by many
7 other investigators?

8 MR. ERNST: Objection.

9 THE WITNESS: I don't think everybody else did
10 a study quite like this one.

11 BY MR. MORIARTY:

12 Q Okay.

13 A So I don't know if it's been reaffirmed. I
14 wouldn't, for instance, if this is a drug study, I
15 wouldn't say it was adequate enough or complete enough
16 or had enough subject matters or have enough controls.
17 It was not really meant to be any of those things,
18 though. You're making it out to be what it isn't.

19 Q Well, you cited it in your report, so that's
20 why I'm asking you about it.

21 Do you agree that substantial increases in
22 serum levels occur following death ir- -- I'm sorry, let
23 me rephrase that. It's badly phrased.

24 The second sentence of their discussion
25 sentence says, "Substantial increases in serum levels

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1 occur following death irrespective of the source of the
2 sample."

3 Do you agree that that has been consistently
4 found --

5 MR. ERNST: Objection.

6 BY MR. MORIARTY:

7 Q -- in these other peer-review scientific papers
8 that I've been asking you about?

9 MR. ERNST: I apologize. I thought you were
10 finished.

11 Objection.

12 THE WITNESS: I am not really sure what they
13 mean by that. I think they are just -- I kind of get
14 the gist of what they are trying to say. I don't know
15 if it's as tight of a relationship as you want it to be.
16 I don't know who's the proponent of the idea
17 extrapolating this Dig level back. I'm certainly not.
18 I was just trying to show that there's a general concept
19 here in which we can rely upon, which is postmortem
20 redistribution, and that's all I was trying to
21 demonstrate. I wasn't trying to create any
22 extrapolation backwards to an exact number.

23 Q Okay. Let me -- are you done with your answer?

24 A Yes, please.

25 Q I thought I asked you this question before.

1 Maybe I didn't.

2 A I've been trying to answer your questions very
3 specifically --

4 Q I'm asking you --

5 A -- without elaborating, so...

6 Q I think I asked you this question that I'm
7 about to ask you, before, maybe I didn't, so let me ask
8 you this now. Okay?

9 I want you to assume that hypothetically, at
10 the campground, for some reason, somebody had been able
11 to draw a serum Digoxin level on Dan McCornack at
12 midnight.

13 A At midnight.

14 Q Okay? Fifteen minutes before he arrested.

15 A Correct.

16 Q All right? Do you have an opinion to a
17 reasonable degree of probability, scientific
18 probability, as to what his serum Digoxin concentration
19 would have been?

20 MR. ERNST: Objection. Multiple objections.

21 THE WITNESS: With what kind of precision?

22 BY MR. MORIARTY:

23 Q Reasonable degree of scientific certainty?

24 MR. ERNST: Same objection.

25 THE WITNESS: If you are saying it's more

1 probable than not that he had a toxic level at the time
2 of his demise, I would probably say yes.

3 BY MR. MORIARTY:

4 Q Do you have an opinion to a reasonable degree
5 of probability as to a number for his serum Digoxin
6 concentration?

7 A I'm not too sure that a number is all that
8 important. It doesn't make any sense to me. Toxic
9 effects occur on a broad range. They are not all that
10 number driven. The human body is not a mechanical
11 machine, per se. It's got a lot of different variables.

12 I believe Mr. McCornack had elevated Dig level
13 irrespective of whatever might have happened with the
14 Dig attack. And I think the reason for that is because
15 of previous blood levels, his Diltiazem and some other
16 issues that I believe put him in a situation where he
17 was maintaining it probably the highest level of Dig
18 that he could maintain. And something that particular
19 night pushed him over into a Dig level that caused him
20 to have these arrhythmias.

21 Q Let me ask this --

22 MR. ERNST: He's not finished yet.

23 MR. MORIARTY: Yes, he is.

24 THE WITNESS: Yeah, I was.

25 MR. ERNST: Okay. Thank you.

1 BY MR. MORIARTY:

2 Q Let me ask this a different way. Do you have
3 an opinion to a reasonable degree of scientific
4 probability as to whether Dan McCornack's serum Digoxin
5 level, if drawn 15 minutes before he arrested, was
6 greater than two nanograms per milliliter?

7 MR. ERNST: I'm going to object. Multiple
8 objections. You are not using a right standard.

9 THE WITNESS: If numbers really matter to you,
10 yes, I would think so. I do think there's -- there was
11 some, and the reason I have that opinion is because his
12 earlier level was --

13 THE REPORTER: I'm sorry?

14 THE WITNESS: -- a trough.

15 (Interruption by the reporter)

16 THE WITNESS: Substitute that for nadir. I
17 don't know why I like that word. It was a trough. It
18 wasn't a peak.

19 I think that he was surviving on a maximum dose
20 of Diltiazem which probably raised his Dig level some,
21 and I think that at the time of his death something was
22 different that was unusual from the previous year.
23 Forty-five-year-old men don't change in health that
24 much, like other age groups are accelerating, like the
25 elderly or geriatric population. So something was

1 different that particular night that caused this
2 particular situation.

3 And as evidence of that, I have a postmortem
4 Dig level that's extremely high. And I think I am using
5 the postmortem Dig level to say that I believe that his
6 Dig level at the time of his demise was in excess of
7 what was toxic for Mr. McCornack.

8 BY MR. MORIARTY:

9 Q What was toxic for Mr. McCornack?

10 A Well, see, this is the whole point of my ten --
11 what is it? My little graph of the different
12 probabilities, arrhythmias. It's a sliding scale. It
13 goes from 1.7 to 3.3 from 10 percent to 90 percent. So
14 there's a sliding scale of probability of arrhythmias
15 that may occur with a rising blood -- Dig level. Serum
16 Dig level. So can you tell exactly what Dig level
17 causes toxicity?

18 I mean, people come in the hospital all of the
19 time asymptomatic on 2.4 or 2.6, 2.8. Others come in
20 terribly toxic at any level over 2. There's a lot of
21 people in the literature, even advocating trying to
22 maintain levels less than 1.5 to try to abate this
23 situation. That's where the postmortem Dig level comes
24 into play. Because it's something he gives a data point
25 to tell us that this gentleman was not necessarily in

1 the low therapeutic range, otherwise this redistribution
2 wouldn't have occurred quite so greatly.

3 In fact, you're talking about going down a
4 concentration gradient. So he had to have substantial
5 Dig stored in order to cause this distribution.

6 And you know, passive -- passive is not like
7 active. A dead person doesn't have any blood flowing
8 around. I don't know if you've ever done this
9 experiment where you put a little piece of colored solid
10 in liquid and wait how long it's going to passively
11 distribute. These are long-term events. They are
12 not -- it always goes up -- down gradient or up
13 gradient.

14 THE REPORTER: "Down gradient"?

15 THE WITNESS: The passive distribution always
16 goes down the gradient.

17 BY MR. MORIARTY:

18 Q Let me ask you a couple questions here.

19 Do you know whether patients can be Dig toxic
20 at levels less than two?

21 A Yes.

22 Q Okay.

23 A I mean --

24 Q They can; right?

25 A They can.

1 Q All right. And there's an overlap, patients
2 can be toxic at less than therapeutic or the high range
3 of the therapeutic and they can be toxic outside the
4 therapeutic range; right?

5 A Absolutely.

6 Q And there are patients who can be outside the
7 therapeutic range and not toxic; right?

8 A That's absolutely true.

9 Q So the therapeutic range in the living in most
10 labs is .8 to 2.0 nanograms per milliliter; is that
11 right?

12 A Well, now, that's a little bit --

13 Q Let's make this simple.

14 Can you show me any medical record in this case
15 for a serum Dig level where the lab did not use .8 to
16 2.0 nanograms per milliliter as the therapeutic range in
17 its lab.

18 MR. ERNST: Which lab are you talking about?

19 Objection.

20 MR. MORIARTY: Any lab in his box.

21 MR. ERNST: Objection.

22 THE WITNESS: I don't know. Most
23 recommendations are for congestive heart failure to be
24 from 0.8 to 1.5.

25 BY MR. MORIARTY:

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1 Q He didn't have CH. He had A-fib.

2 A That's absolutely correct. And for -- to
3 control an atrial fibrillation, there's some debate as
4 to what particular levels you should maintain. These
5 doctors have been driven by the idea that a high Dig
6 level was the most appropriate way to treat this
7 patient.

8 Q Perhaps you misunderstand my question.

9 A Maybe I did.

10 Q I'm not talking about the therapeutic goal that
11 the doctors had. The lab slips, when the blood is
12 drawn, all have a therapeutic range on them against
13 which the patient's level is measured. Okay?

14 A Okay.

15 Q Do you know that?

16 A I know that.

17 Q And in every lab in this case, it's .8 to 2.0
18 nanograms per milliliter; correct?

19 MR. ERNST: Objection.

20 THE WITNESS: I think the -- I think you're
21 misinterpreting that, but, okay. I mean, they generally
22 describe toxic events to occur at 2.0 or greater.
23 Sometimes some labs even report 2.5 or greater.

24 BY MR. MORIARTY:

25 Q Mr. Gibson, you are reading way more into my

1 question. Don't interpret my question. In a lab
2 slip --

3 MR. ERNST: I --

4 BY MR. MORIARTY:

5 Q In a lab slip, whether it's a BUN, a
6 creatinine, a red blood cell count or a Dig level,
7 there's a therapeutic range on the slip; correct?

8 A Correct.

9 Q And then the patient's result is compared with
10 that lab's therapeutic range of those various measures;
11 correct?

12 A Right. And I see --

13 Q In this case, have you seen any lab slips for
14 serum Digoxin concentrations on which the therapeutic
15 range on the lab slip is something other than .8 to 2
16 nanograms per milliliter?

17 A Okay. You are just talking about the one lab
18 that we have in this case done by NMS labs. Is that
19 what you're talking about?

20 Q Well, what about the one that you have in your
21 own report?

22 A Well, not all labs report 0.8 to 2.0. Some --

23 Q I'm asking about the ones in this case.

24 MR. ERNST: We're --

25 THE WITNESS: I'm sorry.

1 MR. ERNST: Objection. You're being
2 argumentative.

3 BY MR. MORIARTY:

4 Q I've asked the same question ten times. I'm
5 asking about the labs in this case. I don't want to
6 debate with you about the thousands I've read in the
7 Digitek litigation or Alabama or Alaska or what they do
8 in any other hospital. I'm talking about in this case.

9 A Okay. So the lab that I reviewed in Dr. -- the
10 doctor's medical records, is that where I got the 1.6?
11 Is that the lab you're talking about?

12 Q I would assume so.

13 A Okay. I don't remember what that lab slip
14 said.

15 Q Did you only see one?

16 A No, I saw about three. That was the last one.

17 Q You don't remember what the therapeutic range
18 was?

19 A No, I really don't.

20 MR. ERNST: I --

21 BY MR. MORIARTY:

22 Q Let's just -- let's assume that the therapeutic
23 range on the lab slip is .8 to 2.

24 A Okay.

25 Q 3.6 isn't even double; correct?

1 MR. ERNST: Objection.

2 THE WITNESS: No, it's not double.

3 BY MR. MORIARTY:

4 Q In all of the literature you reviewed to
5 prepare for your opinions in this case, what were the
6 magnitudes of increase following death of the Dig
7 levels?

8 MR. ERNST: Objection.

9 BY MR. MORIARTY:

10 Q What was the highest?

11 A You know, there was a report of a child that
12 did not die that had a very high level. Could you give
13 me a second?

14 Q Well, if they didn't die, that's not an issue.
15 I'm talking about postmortem redistribution.

16 MR. ERNST: You are arguing. I think we should
17 take a break.

18 MR. MORIARTY: I'm not arguing.

19 MR. ERNST: I'm going to place this on the
20 record. You're becoming argumentative. I think I'd
21 like to take a break for five to ten minutes.

22 MR. MORIARTY: We can take a break, but, Don,
23 he's not listening to my questions.

24 MR. ERNST: Like I say --

25 THE REPORTER: On the record?

1 MR. MORIARTY: Yes.

2 MR. ERNST: We're arguing.

3 You may not like his answers and you interrupt
4 him when he's answering. So let's cool down. Let's
5 have a five-minute to ten-minute break. Let's see if
6 some food is here. It's 12:09. We've been going for
7 three hours. Let's see if we can get some food and cool
8 down just a little bit.

9 MR. MORIARTY: That's fine, but he's not
10 listening to my question.

11 MR. ERNST: You know what, that's an argument.

12 MR. MORIARTY: Fine.

13 MR. ERNST: You're arguing again.

14 (Recess.)

15 BY MR. MORIARTY:

16 Q Let's assume that we had data available,
17 whether it was part of a study or in a case like this --

18 A Sure.

19 Q -- where a predeath level had been drawn and we
20 knew it was 1.5, and a postmortem level had been drawn,
21 and we know that it was three. Okay?

22 A Okay.

23 Q So the order of magnitude of the redistribution
24 would be a simple --

25 A Two.

1 Q -- doubling; correct?

2 A Sure.

3 MR. ERNST: Are you going to add times to that
4 or just --

5 MR. MORIARTY: I'm trying to keep it simple.
6 Thanks for your help.

7 Q Okay. Now, in the material that you reviewed
8 to formulate opinions in this case, did you see comments
9 by the authors based on their data what sort of orders
10 of magnitude there were in the postmortem results?

11 MR. ERNST: I'm going to object.

12 THE WITNESS: Well, I think I kind of tried to
13 answer that with my little graph that I have on page 8
14 showing the orders of magnitude. I mean farther away
15 you are from the central depository which would be
16 myocardium, given the length of time between the
17 distance to, you know, that drug level has a higher
18 multiplier.

19 Q Okay.

20 A Well, so if you had a femoral artery, a femoral
21 stick that was a three, you know, the farther away it is
22 from that repository, you're going to have a bigger --
23 and it's high, it's going to be a bigger. So how could
24 I phrase this? I'm trying to make it exactly correct.
25 These Vorpahl and et al., did -- they put their

1 multipliers for femoral vein at 1.42. So they were
2 saying in about one and a half times the femoral would
3 be the expected serum blood level at the time of death.
4 But you know, there's a lot of variability in that.

5 Q Sure. And the maximum draw time there was 22.4
6 hours; right?

7 A Correct.

8 Q So but, for example, from --

9 A Can I just ask a question about the assumption
10 of that question? The assumption in that question is
11 the length of time has a greater -- greater effect?
12 Because you can only go towards the concentration
13 gradient. At some point, let's say you took a blood
14 level two years -- well, an infinite amount of time, it
15 would all be the same all over the body, theoretically;
16 correct? Sort of?

17 Q I'm not sure who's deposing who now.

18 A Okay.

19 Q So I'll ask the question.

20 A Okay. Go ahead.

21 Q Nowhere in any scientific literature that
22 you've ever seen is there a statement about when it
23 reaches equilibrium in postmortem redistribution?

24 A Well, that's true.

25 Q Okay.

1 So --

2 MR. ERNST: He wasn't finished answering your
3 question. You said okay.

4 THE WITNESS: It's true, because I didn't see
5 anybody even ask the question.

6 BY MR. MORIARTY:

7 Q Okay. In order to study that you would have to
8 have an antemortem level and then a sequential number of
9 postmortem levels drawn over who knows what amount of
10 time until that equilibrium is reached?

11 A That's correct.

12 Q And nobody has ever done that?

13 A Nobody has ever done that.

14 Q But in the literature I've read to you, time
15 matters so that a draw at one hour is going to be
16 different than a draw at ten hours?

17 A Correct.

18 Q So I want to get back to quantification. In
19 the Cook and Braithwaite article that we marked earlier
20 in here --

21 MR. ERNST: Exhibit Number?

22 MR. MORIARTY: Don't know.

23 THE WITNESS: Hold on a second.

24 MR. MORIARTY: It's sitting right there.

25 THE WITNESS: "G."

1 BY MR. MORIARTY:

2 Q Page 284, first paragraph about halfway down,
3 it says, "In several cases, the difference between the
4 two concentrations was immense."

5 Do you see that?

6 A Uh-huh.

7 Q It's not very mathematically precise?

8 A No.

9 Q So in the Vorpahl article, it says that
10 "Substantial increases in the serum levels occur
11 following death."

12 Did you see that? That's at page 333 of the
13 Vorpahl article.

14 A 333.

15 Q Second sentence.

16 A At the top? Substantially increases. Sure.

17 Q And then did you find in your research that
18 generally people believe that the heart tissue to heart
19 blood ratio in the liver is 30 to 1?

20 MR. ERNST: Objection.

21 BY MR. MORIARTY:

22 Q I'm sorry?

23 A It's some number like that. Thirty to 40 is
24 what I recollect.

25 Q And does that give some frame of reference

1 mathematically to the potential of redistribution?

2 A Yes, because that essential repository in which
3 this passive redistribution will occur.

4 Q So do you -- have you done any calculations or
5 do you have an opinion to a reasonable scientific
6 probability about what the tissue concentrations for
7 Dan McCornack would be given the fact that he was taking
8 .5 milligrams of Digoxin per day?

9 MR. ERNST: Objection.

10 THE WITNESS: So .5 is a pretty substantial
11 dose. Yeah. It's not the normal 1.25 or .25 daily that
12 we see so commonly. So I would anticipate that his
13 myocardium would contain a substantial amount of
14 Digoxin, yes. If that's your question. I can't
15 mathematically go anywhere with that.

16 BY MR. MORIARTY:

17 Q You can't quantify it?

18 A No.

19 Q But substantial?

20 A Yes.

21 Q And I don't want to get too far off on the
22 clinical cardiology path, but would you assume that he
23 was given those doses because that's what doctors Lemm
24 and Von Dollen believed was necessary for his control of
25 his atrial fibrillation?

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1 A Yes. I mean, I looked at that issue, and I
2 think it kind of came up earlier about blood levels.
3 There is some literature indicating that the high
4 normal, the 1.5 to 2.0 is the range you want to put a
5 person in who has this disease state. And these doctors
6 were very aggressive. I mean, even in their Diltiazem
7 choice they pushed it to the max.

8 Q Are you familiar with any literature in which
9 the magnitude of postmortem redistribution was up to ten
10 or more times the antemortem level?

11 MR. ERNST: Objection.

12 THE WITNESS: I didn't see that, no.

13 BY MR. MORIARTY:

14 Q Do you have a second article by Dr. Koren here,
15 not the rat article, but another one?

16 A I do not. Is there one?

17 Q Yes. I thought I understood this, maybe not,
18 go back to page 2 of your report.

19 A There.

20 Q You've said a couple times, I believe, that
21 this Digoxin level of 1.6 you believed was a trough
22 level?

23 A I believe it is, yes.

24 Q What's the basis for that statement?

25 A The timing of the day, and the -- the time of

1 the day. I don't think he -- I don't think it's -- even
2 if he took his dose at 8 o'clock, this would still be
3 close to trough level. I mean, the peak -- the peak
4 occurs at, what, two to four hours or four to six hours.
5 I forget what I --

6 Q Well --

7 A There's a lot of dispute as to that, but it
8 seems to me --

9 Q If -- are you done?

10 A No, go ahead, please.

11 Q If you assume, according to Kathy McCornack's
12 testimony, that Dan faithfully took his Digitek after
13 breakfast every morning, and you assume he had breakfast
14 that morning, he would have taken his Digitek within a
15 couple hours of this draw; correct?

16 A Yes.

17 Q In which case at least some of it would be
18 metabolized and it would not be a trough level?

19 A Correct. But a lot of times these samples,
20 these kind of blood draws -- um, first of all, I think
21 if he was asked to go do this he was probably asked not
22 to take his dose that day, but it's -- I'm not sure
23 about that. A lot of these kind of lab tests are done
24 fasting. And there are other levels that the doctors
25 were looking at, like triglycerides that you need to

1 take fasting. And so I would suspect, in fact, I think
2 he was fasting at the time he took this, and that's the
3 assumption I made.

4 Q But that's an assumption you made; correct?

5 A Well, and I wasn't there, so I really don't
6 know if he took the tablets.

7 Q Okay. That's fine.

8 Let's go to page 9 of your report. What you've
9 done here, is at the end of page 8 you are talking about
10 that he wasn't on -- you're going through the Goodman
11 and Gilman factors and trying to eliminate things;
12 right?

13 A Correct.

14 Q Is there anywhere on page 8 or 9 of your report
15 where you account for the possibility of an arrhythmia
16 from his underlying disease?

17 A It's in my report, no.

18 Q Okay. So you say here the last factors to
19 consider are an incorrect administration of the evening
20 dose or abnormality in the tablet ingested; right?

21 A Correct.

22 Q So have you formulated an opinion to a
23 reasonable probability as to what the dose of Dan's
24 tablet was the evening of the 22nd of March?

25 A Well, I assumed that he took one tablet. And I

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1 make that assumption because he used a tablet dispenser.
2 He filled that tablet dispenser when he was sober. He
3 was on a trip. That was the only supply of drugs. I
4 didn't think he would take more than one. So that led
5 me to believe that his dose that evening would be the
6 one tablet of 0.25.

7 Q Well, his prescription was for .250, twice a
8 day. Okay?

9 A .25.

10 Q Yes.

11 A Yeah.

12 Q So what I'm asking you is, do you have an
13 opinion to a scientific probability what the dose of his
14 medication was that he took the evening of the 22nd?

15 MR. ERNST: Objection.

16 BY MR. MORIARTY:

17 Q Was it what he was prescribed or was it higher
18 or was it lower?

19 A I think he took what he was prescribed.

20 Q Okay. So .250?

21 MR. ERNST: Well, I'm going to object. I think
22 it's --

23 BY MR. MORIARTY:

24 Q Do you have an opinion to a reasonable
25 scientific certainty as to the dose of the tablet he

1 took on the morning of the 22nd?

2 A I think he took a .25.

3 Q Do you have an opinion to a reasonable degree
4 of scientific probability as to the dose of any tablets
5 he took on the 21st?

6 A You mean like a --

7 MR. ERNST: I'm going to object.

8 BY MR. MORIARTY:

9 Q The day before he died?

10 MR. ERNST: Are you talking about a different
11 tablet? I'm not clear what you're asking.

12 THE WITNESS: Yeah, I'm not clear either. Let
13 me answer this way.

14 BY MR. MORIARTY:

15 Q I thought my question was crystal clear.

16 A It's not.

17 I believe he took his prescribed medication as
18 directed, and he took one tablet in the morning and one
19 tablet in the evening as dispensed by the pharmacy.

20 Q That wasn't my question.

21 A Dang it.

22 Q My question was, what's the dose? Dose.
23 What's the dose? We know what he was prescribed.

24 MR. ERNST: Well --

25 BY MR. MORIARTY:

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1 Q And we know what he took. You're assuming he
2 took one?

3 A Right.

4 Q Okay.

5 A And the dose would be 0.25 if that's one.

6 Q Thank you. That was my opinion, okay.

7 A Okay.

8 Q Or my question.

9 Do you have an opinion as to the dose of the
10 tablets he took on the 21st, which is the full 24-hour
11 period the day before he died?

12 A I believe he took the exact same.

13 Q So it's your opinion, according to what you
14 have at the bottom in your bullet points, that
15 Mr. McCornack became toxic on Digoxin taken as
16 prescribed as to timing and dose; correct?

17 A Yes.

18 Q And then he got essentially .5 on the 21st, and
19 .5 on the 22nd, and he became Dig toxic on those doses;
20 correct?

21 MR. ERNST: Objection. Objection. That was
22 the prescribed dose.

23 BY MR. MORIARTY:

24 Q Well, go on.

25 A Well, I mean, I know you are trying to corral

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1 me into a little corner here, and I don't know where the
2 corner is so it's hard for me to answer.

3 Did he take a tablet labeled 2.5? Yes. He
4 took them twice a day religiously, consistently. That
5 was probably -- there might have been an earlier time
6 where there was some issue that I read about. But I
7 believe he took these tablets in the morning and evening
8 that were put into his pill dispenser and they were
9 labeled 0.25.

10 Q Well, Mr. Gibson, I never asked you if any of
11 the last five minutes of my questions about this very
12 topic about labeled or unlabeled. I asked you what the
13 dose was, whether you had an opinion to a probability
14 what the dose was --

15 A Okay.

16 Q -- and you've said .25, .25, .25?

17 A Correct.

18 Q Four doses over two days?

19 A Correct.

20 Q So if I were to walk out of here right now,
21 your opinion is that he got those doses, not that his
22 tablets were defective and he got some other doses?

23 Now are you going to tell me that you
24 misunderstood my question and you believe he got some
25 other dose than what you just testified to?

1 A Your definition of dose is probably different
2 than mine.

3 Q Oh. It's a Clinton thing?

4 A No.

5 Q Go on.

6 MR. ERNST: No.

7 MR. MORIARTY: I'm going to be clear with my
8 question.

9 MR. ERNST: Let him answer his question.

10 BY MR. MORIARTY:

11 Q I'm going to be clear with my question.

12 I don't want to know what you think the labeled
13 dose was. I want to know if you have an opinion to a
14 reasonable scientific probability what the dose of his
15 Digitek was that he took the evening of the 22nd, the
16 morning of the 22nd, and the two doses on the 21st, the
17 actual dose ingested. Okay? Which is what I've already
18 asked you.

19 A Now, I know you get real mad at this, but the
20 term dose means what you pass through your mouth. Not
21 what you absorb. I think what you're really asking is,
22 was there a change in the bioavailability of that
23 particular dose.

24 Q That's not what I'm asking you. Okay?

25 A If you're asking me what the dose was --

1 MR. ERNST: You've interrupted his answer
2 again.

3 MR. MORIARTY: He's telling me --

4 THE WITNESS: If you mean, did he take -- if he
5 took those tablets exactly as prescribed, then I would
6 say that's what I believe to be true.

7 BY MR. MORIARTY:

8 Q Okay. I'm not asking you about the
9 bioavailability of the tablets. Okay? I'm asking you
10 about the dose of Digoxin.

11 A Correct.

12 Q The active pharmaceutical ingredient in those
13 four tablets.

14 A Dose means what passes the lips and goes down.

15 Q Yes.

16 A Yes.

17 MR. ERNST: I think it is still unclear on the
18 record. You guys are ships --

19 MS. AHERN: Can you ask him one more time now
20 that we've cleared it up?

21 MR. MORIARTY: I think --

22 THE WITNESS: I think I've answered it three
23 times.

24 MR. ERNST: He's thinking one thing --

25 MR. MORIARTY: No, we are thinking the same

1 thing.

2 MR. ERNST: I disagree.

3 BY MR. MORIARTY:

4 Q Here's my next question. Is it your opinion
5 that the bioavailability of the .250 Digitek that he
6 ingested over the course of those two days was different
7 from its FDA-approved formulation?

8 A I believe it could -- yes.

9 Q I want to know everything that is the basis of
10 your opinion to a reasonable degree of scientific
11 probability that that is the case.

12 A Okay. Mr. McCornack had been on this drug
13 regimen for a long period of time. Over a year. He had
14 a very substantial dose of Digoxin. This is not a
15 person taking a minor dose. He's taking a substantial
16 dose of Digoxin.

17 He's also taking Diltiazem, which may have
18 raised his Dig levels a little bit. But if the
19 Diltiazem would have caused Digoxin toxicity, it would
20 have occurred at some point five to seven times the
21 steady state, somewhere around there, at that point. He
22 had been living with a consistent Dig level based on
23 this drug regimen that somehow got changed on the day of
24 his death. And one of the possibilities is that the
25 formulation was in error. If there's an error in the

1 formulation, the bioavailability goes up, if he was
2 absorbing 60 percent. Most bioavailability described
3 for Digoxin is somewhere between 60 and 40 percent --
4 sixty and 80 percent, I'm sorry. Sixty and 80 percent.
5 I'm terrible at numbers today. Sixty and 80 percent.
6 If these tablets were made in a way that would have
7 resulted in 100-percent absorption, that would have
8 changed his Dig levels.

9 I think Mr. McCornack was right on the verge of
10 having a toxic level of Digoxin except for, I think this
11 is consistent with his history, that he was -- he was on
12 this dose, it was very high, the doctors intended it to
13 be high to treat the arrhythmias. And something
14 occurred in that particular night that made it go into a
15 level that made him toxic.

16 One of the answers to that question is that the
17 tablets had a formulation that changed the
18 bioavailability.

19 Q Are you done with your answer?

20 A I am.

21 Q So that's a possibility?

22 A Probability.

23 Q Okay. So have you seen any dissolution testing
24 to indicate that there was a problem with the
25 bioavailability of Digitek?

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1 A Dissolution tests are not the same as
2 bioavailability tests.

3 Q I'm asking -- let me ask it a different way.

4 Have you seen any indications that dissolution
5 testing for Digitek was outside of its specifications?

6 A No, I have not.

7 Q Have you seen any testing results to indicate
8 that assay for Digitek was outside of its
9 specifications?

10 A No, I haven't.

11 Q Have you seen any --

12 A I might be wrong in a minute.

13 Q -- test results to indicate the content
14 conformity tests for Digitek were outside of its
15 specifications?

16 A Yes. It looks like there was some issues as to
17 formulation.

18 Q I'm asking content uniformity testing. A very
19 specific time of testing.

20 A When I prepared this result, I -- this report,
21 I'm sorry. I didn't think that was my job to try to
22 determine whether or not. He has an expert for that.

23 Q Then let me get to that.

24 Are you relying, for your opinion about
25 bioavailability, on David Bliesner's report?

1 MR. ERNST: Objection. Did you include the
2 exhibits in his deposition?

3 MR. MORIARTY: He hasn't read Bliesner's
4 deposition.

5 Q Are you -- that's what he testified to a couple
6 hours ago.

7 Are you relying, for your opinion on this
8 bioavailability issue, on the report of
9 David Bliesner --

10 A Yes. In his report.

11 Q -- and any exhibits to Mr. Bliesner's report?

12 A I'm sorry. In his report, it's pretty clear
13 they were having production problems, and that
14 formulations was one of the issues.

15 Q I would like you to show me somewhere in that
16 report where it says that there were bioavailability
17 issues with Digitek?

18 A I don't know if they did any bioavailability
19 tests.

20 Q What's the basis for your opinion in that
21 report that there was a bioavailability --

22 MR. ERNST: Take your time.

23 BY MR. MORIARTY:

24 Q -- issue with Digitek?

25 MR. ERNST: Do you have your chart? This is

1 his. This is yours, right?

2 MR. MORIARTY: It's not mine.

3 THE WITNESS: It's mine.

4 MR. ERNST: Okay.

5 THE WITNESS: Thank you.

6 MR. ERNST: Take as much time as you need.

7 MR. MORIARTY: Found it yet?

8 MR. ERNST: He's got time.

9 MR. MORIARTY: All I asked is if he found it
10 yet. He can take all of the time he wants. If he
11 hasn't found it, he can tell me he hasn't found it.

12 Q Have you found it yet?

13 A I found some stuff.

14 Q Okay. Tell me what in there --

15 A So on item number 35 in Dr. Bliesner's report,
16 he indicates that Actavis annual review for 17 adverse
17 effects, and then the very following one, which is 36,
18 which is a blended.

19 Q Well, first of all, do you know what the 17
20 adverse events were that he's describing?

21 A Not specifically.

22 Q Do you know whether the FDA ever was concerned
23 about any of those 17 adverse events?

24 A Is that relevant? I don't know it would have
25 crossed my mind.

1 When I reviewed the report, I was just looking
2 for abnormalities in production and whether or not some
3 other experts going to come in and testify that there
4 was a problem with formulation of this drug that might
5 cause -- that's the one I showed him. 36.

6 Q So you're referring to 36, this paragraph about
7 blend uniformity fillers?

8 A Right. That's just one of them.

9 Q Are you an expert in blend uniformity sampling?

10 A No.

11 Q Have you ever done it?

12 A No.

13 Q Have you ever read anything about it?

14 A I've read about formulation changes and how
15 they affect the absorption of Digoxin, but that's all.

16 Q My question was whether you have ever read
17 anything about blend uniformity failures, or blend
18 uniformity at all?

19 A Well, you know, there's a change in the
20 formulation of the drug, I have read about issues with
21 Dig in the past where there was formulation changes.

22 Q Do you know anything about whether these blend
23 failures had to do with technical testing issues or
24 actual blend failures?

25 A There's where I was going to rely on the other

1 expert for that sort of thing.

2 Q So you would defer to Mr. Bliesner?

3 A I would refer to Mr. --

4 Q Dr. Bliesner?

5 A Dr. Bliesner, yes.

6 Q As to whether or not he's indicated any sort of
7 actual change in the formulation?

8 A Right.

9 Q Did you see in the Mason, Von Dollen
10 depositions their opinions that they did not see any
11 clinical signs or symptoms of Digoxin toxicity in
12 Mr. McCornack the night he died, or the day he died?

13 MR. ERNST: I'm going to object.

14 THE WITNESS: So the doctor --

15 MR. ERNST: They didn't see him the day he
16 died.

17 THE WITNESS: They didn't see him the day he
18 died or any time soon.

19 BY MR. MORIARTY:

20 Q I asked if he saw in their depositions where
21 they testified that they didn't see any evidence of
22 Digoxin tox -- clinical signs of Digoxin toxicity the
23 day he died?

24 A They didn't see him the day he died.

25 Q Let me go back to square one. We have to drag

1 it out.

2 MR. ERNST: No. You're --

3 BY MR. MORIARTY:

4 Q You know that Dr. Von Dollen had some
5 descriptions of what happened to Dan McCornack the day
6 he died; correct?

7 A Oh, sure. Okay.

8 Q And Dr. Mason had the sheriff's department do
9 an investigation; correct?

10 A Okay.

11 Q And Kathy McCornack has testified and has
12 spoken to Dr. Von Dollen about what happened the day Dan
13 died; correct?

14 A Uh-huh.

15 Q So that when I was in California in the fall of
16 2009 taking the depositions of Mason, Von Dollen and
17 even Lemm, they had information about Dan's clinical
18 condition the day he died. Do you know that?

19 MR. ERNST: Objection.

20 BY MR. MORIARTY:

21 Q Do you know that?

22 A I think -- from reading their depositions I
23 think I knew that. I didn't zero in on that part. I
24 believe that to be true.

25 Q Did -- were you done with your answer?

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1 A I mean, I didn't zero in on it, so I'm not as
2 sure as I should be.

3 Q Did Doctors Mason and Von Dollen both testify
4 in their depositions that they had not seen any evidence
5 that Dan had Digoxin toxicity on the days before he
6 died?

7 MR. ERNST: Objection.

8 THE WITNESS: And I do not remember.

9 BY MR. MORIARTY:

10 Q Okay. Thank you.

11 Just so we're clear, this level of 3.6 was
12 based on a 78-hour-after-death blood draw; correct?

13 A Correct.

14 Q 3.6 is not the level of Dan's Digoxin at the
15 time he died; correct?

16 MR. ERNST: Objection.

17 THE WITNESS: Correct.

18 BY MR. MORIARTY:

19 Q So, in your last bullet point on Page 9, what
20 are you talking about when you refer to clinical
21 conditions?

22 A Well, I mean, there's a gentleman that was
23 taking Digoxin. His postmortem blood Digoxin serum
24 level is high. He was on a very -- fairly high dose as
25 a routine. He was also on Diltiazem. I think -- and

1 had an arrhythmia that killed him. I think that's the
2 clinical condition.

3 Q Are you done with your answer?

4 A Uh-huh.

5 Q So you're not talking about clinical conditions
6 as in blurred vision, nausea, vomiting, or --

7 A Correct.

8 Q -- anything like that?

9 Okay. Okay. I haven't had a chance to reread
10 this, but let me mark it as an exhibit.

11 This is another article by Dr. Koren, the same
12 Dr. Koren, the same Dr. Koren who authored the article
13 that you reviewed and quoted in your paper. Okay? This
14 was also published, I believe, in 1985.

15 Have you seen this article before?

16 MR. ERNST: I'm going to --

17 MR. MORIARTY: I've marked it Exhibit I.

18 (Defendants' Exhibit I was marked for
19 identification.)

20 MR. ERNST: I'm going to object. He's
21 testified he hasn't. I think this line of questioning,
22 I'm going to object to. If you want to give me a
23 continuing objection on this issue?

24 MR. MORIARTY: Sure.

25 Q Have you seen the article? That's my first

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1 question.

2 MR. ERNST: Do you have a copy for me?

3 MR. MORIARTY: That's all I have. We'll make a
4 copy when we're done.

5 THE WITNESS: No, I can say that I probably
6 didn't see this article.

7 MR. MORIARTY: All right.

8 MR. ERNST: May I look at it?

9 MR. MORIARTY: What?

10 MR. ERNST: Are you done? May I look at it if
11 you --

12 BY MR. MORIARTY:

13 Q The only sentence I want to ask you about on
14 this, it says, "An attempt to prove Digoxin intoxication
15 as a cause of death may be hampered by the fact that
16 postmortem levels may be 1.5 to ten times higher than
17 antemortem levels."

18 Do you agree or disagree with that statement?

19 MR. ERNST: I would object.

20 THE WITNESS: I don't know if I can agree or
21 disagree. I would have to spend some time and try to --
22 seems awfully high. I don't know.

23 BY MR. MORIARTY:

24 Q Well, have you done any independent research
25 about the degree to which Digoxin levels can increase?

1 A Well, when I --

2 Q -- postmortem?

3 A When I started looking at the literature, I
4 didn't really think that you would be asking me
5 questions to extrapolate backwards on this Dig level.
6 The Dig level is what it is, and it's just a data point.
7 It could be ten times greater. It could be half as
8 much. I don't know. There's a lot of factors involved
9 here.

10 Q Well, does it matter?

11 A Does it -- does it matter?

12 Q Yeah.

13 A What his Dig level is? Yes. But Dig toxicity
14 is a clinical condition that you, you know, there's
15 people with Dig levels all over the board, some with
16 symptoms, some without.

17 Q So, if, for example, the degree of magnitude
18 was just double in the postmortem period in this case,
19 even if there was some mathematical way to extrapolate
20 back, you would simply say that it was what, 1.8?

21 MR. ERNST: Objection.

22 THE WITNESS: Yeah, but you're just -- you're
23 starting to treat numbers now. I mean, it could be that
24 he was at a 1.8 and the change of formulation drove him
25 to 1.9, and that was enough to put him into the

1 arrhythmia.

2 BY MR. MORIARTY:

3 Q Okay.

4 A So it's not mathematical.

5 Q Okay. All right.

6 MR. ERNST: How much longer do you expect to
7 be?

8 MR. MORIARTY: I don't know.

9 THE WITNESS: Do you have a maximum time you
10 can type?

11 MR. MORIARTY: Yes, and it's long. Longer than
12 I will take. It's essentially like two days' worth.

13 THE WITNESS: I'm sorry, I meant the hands.
14 Not what's allowed by the law.

15 BY MR. MORIARTY:

16 Q What I'm doing here, Mr. Gibson, is looking
17 through things that you cited in your report to make
18 sure that I've asked you about them.

19 A Okay.

20 Q Okay? And just going through this quickly, is
21 a quick way to make sure that's happening. So if you
22 want to take -- well, I prefer you just sit here.

23 A I'll just sit here.

24 Q Okay.

25 A I'm getting paid.

1 Q Go to -- I think it's your cite 10. I tried to
2 do my binder according to your footnotes. It should
3 be --

4 A Ellenhorn and Barceloux.

5 Q Got me. Ellenhorn and Barceloux. That's it.
6 Page 204.

7 A I'm impressed you found a copy of the book.
8 What page again?

9 Q 204. I hope we have the same edition.

10 A I don't think there were any other editions. I
11 might be wrong. Okay. I'm there.

12 Q Says, "Laboratory serum Digoxin levels"?

13 A Yes.

14 Q "Therapeutic Digoxin levels are .8 to 2
15 nanograms per milliliter. Do you see that?

16 A Yes.

17 Q Do you agree or disagree?

18 A I think there's some literature to indicate
19 differently, but I'll agree with that.

20 Q Okay. "Serum levels four hours after I.V.
21 administration and six hours after oral ingestion
22 correlate best with the effect of therapeutic setting."

23 Do you see that?

24 A Yes.

25 Q Do you agree with it?

1 A Yes.

2 Q It says here, "Acute overdoses usually involve
3 toxic serum levels exceeding two nanograms per
4 milliliter"?

5 A Correct.

6 Q "Levels over 15 nanograms per milliliter
7 indicate serious intoxication."

8 Do you agree with that?

9 A That's serious, yes.

10 Q I didn't ask you this before, but when we were
11 talking about this bioavailability issue, can you tell
12 me whether the -- let me try to make this question as
13 simple as I can.

14 A Okay.

15 Q Working backwards from the dose he took at
16 dinnertime on the 22nd of March of 2008, when did the
17 tablets have a different bioavailability than the
18 FDA-approved specifications?

19 MR. ERNST: Objection; compound.

20 THE WITNESS: There's no way for me to tell.

21 BY MR. MORIARTY:

22 Q All right. Well, you know that -- well, okay.
23 You don't have an opinion to a reasonable
24 scientific probability on that issue?

25 A When the tablets became nonconforming?

1 Q Yes.

2 A No.

3 Q So how many nonconforming doses of .250 Digitek
4 did Dan McCornack ingest?

5 A Well, see, one of the problems with this case,
6 it could be that some were nonconforming and some were
7 conforming, I don't really know. That could make a big
8 difference if every other one was nonconforming or there
9 was some plethora of those kind of combinations.

10 But what would have come -- if all things being
11 equal, would have come to steady state at approximately
12 five to seven times the halflife. So when that drew him
13 over the level that was toxic for him, he could have
14 been on the ascending part of that when he had his
15 arrhythmia. There's no way to tell.

16 Q I need to leave here and make sure I understand
17 what you just said.

18 A Okay.

19 Q Do you have an opinion to a reasonable
20 scientific probability as to how many doses of
21 nonconforming Digitek Dan McCornack ingested?

22 A I do not.

23 Q Now, I did not ask you about your cite 36,
24 which is the Pounder and Jones article called
25 "Postmortem Drug Redistribution, a Toxicological

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1 Nightmare"?

2 A Yeah.

3 Q But that is one of the things that you cited
4 and relied upon as an authority in your report; correct?

5 A Correct.

6 Q I didn't ask you about Dr. Leikin's paper cite
7 37, but that is one of the things you cited and relied
8 upon for purposes of your report; correct?

9 A Yes.

10 Q Cite 38 is the Hilberg article; correct?

11 A Yes.

12 Q And in that article it says, "The phenomenon of
13 postmortem drug redistribution makes interpretation of
14 drug concentrations found in postmortem blood samples
15 difficult. Ignorance of this phenomenon may well lead
16 to erroneous interpretations."

17 Do you agree with that?

18 A Yes.

19 Q I don't think I asked you any questions about
20 41, which is the Holt and Benstead article. Was that
21 something that you read and relied on for purposes of
22 your report?

23 A Partially, yes.

24 Q All right. And 48 is the Shepherd. And the
25 48, the Shepherd article, is something you cited and

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1 relied upon in drafting your report; is that right?

2 A Partially, yes.

3 Q And lastly, on this line of questions, tab 49
4 from your report or cite 49 is a Kennedy article;
5 correct?

6 A Yes.

7 Q And can you pull that up for me, please, in
8 your stack?

9 A I'm sure it's in here somewhere, but --

10 Q I'm going to read to you from page 185 of that
11 article.

12 A Thank you. That will save me. It's a simple
13 sentence.

14 MR. ERNST: Do you have a copy for him?

15 MR. MORIARTY: He has his own copy.

16 MR. ERNST: I'm not sure he does with him.

17 BY MR. MORIARTY:

18 Q Okay. I'm going to read this, and then I'll
19 hand it to you and make sure I read it correctly.

20 "With the possible exception of paracetamol, it
21 is difficult to find any drug concentration range that
22 has been reliably associated with toxicity and death."

23 Do you agree with that?

24 MR. ERNST: Objection.

25 THE WITNESS: Any drug concentration? I mean,

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1 taken out of context, no. There's lots of paracetamol
2 for just Tylenol poisonings all of the time.

3 We have a little chart at the pharmacy that you
4 can see how much acetylcysteine to be given based on the
5 ingestion in the blood levels.

6 BY MR. MORIARTY:

7 Q Okay. Just wanted to know if you agreed or
8 disagreed with what you cited in your report?

9 A It's kind of taken out of context, though.

10 Q At page 186 of the Kennedy article, your cite
11 49, it says, "Back calculation of drug doses from a
12 single sample is virtually impossible."

13 Do you agree with that?

14 A Yeah. I've been saying that.

15 MR. ERNST: Objection.

16 BY MR. MORIARTY:

17 Q Those blend uniformity tests that Dr. Bliesner
18 referred to in paragraph 36 of that report, did you look
19 at those blend uniformity tests?

20 A No, I left -- I left that part of the analysis
21 to Mr. Ernst and his other experts.

22 Q Did you look at any poison control -- I'm
23 sorry.

24 Did you look at any poison center data to see
25 whether there had been spikes in Digoxin toxicity

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1 anywhere in the United States --

2 A No, I did not.

3 Q -- in 2006 through 2008?

4 A I did not.

5 Q Are you familiar with the statistics on which
6 drugs lead to the highest rate of adverse drug events?

7 A I'm familiar that such a list does exist. I
8 saw one about a year ago. Didn't particularly remember
9 the drugs on the list.

10 Q Do you know where Digoxin falls on the list?

11 A No.

12 Q Can patients develop Digoxin toxicity taking
13 normal prescribed doses of a drug?

14 MR. ERNST: Objection.

15 THE WITNESS: If there's a change in the
16 metabolism, like, let's say, for instance, they develop
17 kidney disease or -- I listed factors in here that I
18 gained from Goodman and Gilman, for instance, if they
19 were taking an antibiotic it could change in absorption
20 or --

21 BY MR. MORIARTY:

22 Q So the answer is yes?

23 A Yes. Thank you.

24 Q Have you read the reports of any of the defense
25 experts in this case?

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1 A I have.

2 Q Whose reports have you read?

3 A Could I state that I've read parts of theirs
4 and parts of some not.

5 Q First, why have you only read parts?

6 A I just received them and haven't had time to go
7 over them.

8 Q When did you get them?

9 A Was it yesterday or the day before?

10 Q Okay. So whose reports have you read parts of?

11 A Um, I don't remember the names, so...

12 Looks like I read a little bit of
13 Matthew Moriarty.

14 Q That's me.

15 A Oh.

16 Q I didn't write a report.

17 A I'm so sorry. I am getting tired now.
18 Amy McMaster.

19 Q Okay.

20 A And --

21 MR. ERNST: For the record, all four that
22 you -- withdraw that statement.

23 THE WITNESS: Did you give me all four that
24 he had?

25 MR. ERNST: I did.

1 THE WITNESS: I do remember looking at briefly
2 four different.

3 BY MR. MORIARTY:

4 Q So McMaster, Heard, Gallanter and Brown?

5 A I believe that's correct. Gallanter. Here's
6 Gallanter, McMaster, Brown, and Heard.

7 Q Do you have a specific opinion to a scientific
8 probability about what the change in the Digitek
9 formulation was? In other words, was it particle size?
10 Was it they left out an ingredient? They added
11 something they shouldn't have? What was the -- do you
12 have an opinion on that or are you deferring to --

13 A I'm going to defer, but I have an opinion about
14 everything. I kind of left that in my report with the
15 idea that some other expert was going to conclude that.

16 Q That's fine.

17 MR. ERNST: You can tell him what you think,
18 but --

19 BY MR. MORIARTY:

20 Q I want to know -- I don't want to know
21 everything you think. I want to know if you have
22 opinions to a reasonable scientific probability. If you
23 want to defer to another expert, you can.

24 A That's what I am.

25 Q If you have an opinion, I'm entitled to know

1 what it is. Okay?

2 So do you know anything about the reliability
3 of that Global --

4 A RPH.

5 Q -- RPH website?

6 A Have I ever manually calculated the same
7 calculations to see if their calculations -- I have not.

8 Q And you don't know whether cardiologists or
9 internists actually use it in practice in making
10 clinical dosing decisions?

11 A I have no idea.

12 Q Do you know anything about the potential
13 sources of error associated with that computer program?
14 What are its error rates?

15 A Well, generally, I know what the equations it
16 supposedly uses. I know what the data from which it
17 came.

18 In pharmacy school I actually spent some time
19 with Dr. Gella (phonetic). I'll spell it for you later.
20 Um, he's one of the people that sort of was leading the
21 charge on developing these equations.

22 Other than that, I -- you know, none of those
23 equations are all that accurate. Have you ever seen a
24 splatter of the data and how it -- and a linear
25 regression, for instance, of that data? I mean,

1 sometimes there's quite a bit of variability. And you
2 don't use those calculations as exactness. They are
3 just directors of clinical decisions. Something to
4 consider, something to guide your next move.

5 MR. MORIARTY: Okay. I want to take a
6 five-minute break, look through my notes, talk to my
7 colleague here, and then decide whether I have any more
8 questions or whether I'm going to turn it over to her.

9 Q But before we break, that's Exhibit B; correct?

10 A It says Exhibit B, yes.

11 Q And every other day.

12 That's the notice for this depo; right?

13 A Okay.

14 Q Have you seen it before?

15 A I probably did. I think it was attached to the
16 subpoena.

17 Q Yes.

18 Did you bring all of the things that you were
19 asked to bring?

20 A It's in the box right here.

21 Q Okay.

22 A Do you want to look at them?

23 Q Can I see the box, please.

24 So there's a bunch of books in here; right?

25 A Yes, there's a bunch of books.

1 Q Are any of these boxes [sic] not cited in the
2 report itself?

3 A All of those books are cited in the report.
4 There's one book that is cited in the report that I do
5 not have a copy in that box. I don't know where it is.
6 But I do have pages. I have this funny feeling I left
7 it on the copy machine, or I made copies of this
8 chapter, that was the Goodman and Gilman 11th Edition.

9 Q The deposition of the two McCornack boys is in
10 your box. Did you read those?

11 A Not yet.

12 Q Deposition of Von Dollen is in here. Did you
13 read that?

14 A Most of it, yes.

15 Q Did you read Lemm's?

16 A Most of it, yes.

17 Q And Kathy's?

18 A Most of it, yes.

19 Q You have a copy of Federal Rule 26 in here?

20 A That was given to me, yes.

21 Q And you have Dr. Mason's depo in here?

22 A Yes.

23 Q Have you read that?

24 A Parts of it, yes.

25 Q Did you --

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1 A That's his bind paper.

2 Q You have the report of Martha Bennett in here;
3 did you read it?

4 A I can't remember. Can I look at it for a
5 minute to refresh my recollection? I skimmed this
6 document. I don't think I looked at it too much when it
7 was given to me.

8 Q And obviously, you have the infamous lab report
9 regarding Mr. McCornack's postmortem blood sample;
10 correct?

11 A Correct.

12 Q And the Diltiazem level was some three times
13 outside what they considered the therapeutic range; is
14 that right?

15 A For those people that do report therapeutic
16 range.

17 Q Well, they did report a therapeutic range. Is
18 it three times outside their range?

19 A It's outside what they say on the report, yes.

20 MR. ERNST: Objection.

21 BY MR. MORIARTY:

22 Q Is it likely that there was postmortem
23 redistribution of his Diltiazem?

24 A Yes.

25 Q Then you have Dr. Mason's stuff.

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1 You have a report from Dr. Kernin; correct?

2 A I'm sorry, I don't remember these names. Yes,
3 I remember looking at this.

4 Q But you don't have his deposition?

5 A No, I don't think I have his deposition.

6 Q Did you bring anything else?

7 A Everything else was in that box, except this
8 binder, if you want to look at this.

9 Q Did you bring all your billing data on this
10 case?

11 A It's in this binder.

12 MR. MORIARTY: That you can have.

13 Don, did you separately disclose the billing
14 data, because I don't remember seeing that?

15 THE WITNESS: I'm bad at billing and I think --

16 MR. ERNST: I probably disclosed his billing
17 rate, if you ask him. But he hadn't prepared his bills
18 yet.

19 BY MR. MORIARTY:

20 Q Do you know how many bills are in here?

21 A Two.

22 Q How many bills have you done?

23 A Two.

24 Q Okay. So the first one is September 30th,
25 2009, for \$875; correct?

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1 A That's correct.

2 Q And the second one is June 13th, 2011, for
3 \$10,500; correct?

4 A Correct.

5 Q And that's all you've billed to date?

6 A To date.

7 MR. MORIARTY: Let's take that break now.

8 (Recess.)

9 BY MR. MORIARTY:

10 Q Mr. Gibson --

11 A Yes, sir.

12 Q -- I have no other questions for you right now.
13 But Ms. Ahern probably does.

14

15 EXAMINATION

16

17 BY MS. AHERN:

18 Q Hi, Mr. Gibson. I do have some questions,
19 mostly just for my own sake to clear up some things.

20 In looking at your report, I just want to make
21 sure that we're clear on what your role was in this
22 case.

23 You know this is the only opportunity we have
24 to ask you about your report and about the opinions that
25 are in your report; right?

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1 A Uh-huh.

2 Q So I'm just trying to understand as best I can
3 before we leave here, because I won't get another
4 opportunity to do that.

5 A All right.

6 Q So your role, what I've heard you say here is
7 that it wasn't your job to ascertain whether or not
8 Dan McCornack actually suffered from clinical toxicity
9 before his death; is that correct?

10 A No, I think the question was did he exhibit any
11 symptoms of clinical toxicity before his death.

12 Q Okay. I thought you said that it wasn't your
13 job to ascertain whether or not he suffered from
14 clinical toxicity before his death, that you relied
15 instead on the opinions of the treating physicians as
16 expressed in their deposition testimony?

17 A No.

18 Q Could you explain to me, then, what your role
19 was with regard to determining whether or not
20 Dan McCornack had clinical toxicity prior to his death?

21 A Okay. I think in relation to that one
22 question, the question was whether or not he suffered
23 from any prodromal symptoms like nausea that comes
24 before toxicity could be diagnosed.

25 (Interruption by the reporter.)

1 MR. MORIARTY: He said prodromal.

2 THE WITNESS: I'll try not to use words that --
3 anyway.

4 So a lot of -- I think the experts in this case
5 especially have relied upon the idea that nausea and
6 vomiting had to precede Dig toxicity. I don't think
7 that's true.

8 BY MS. AHERN:

9 Q What do you think?

10 A I think there are some people that can be Dig
11 toxic without those particular symptoms.

12 Q How do you define Digoxin toxicity from a
13 clinical standpoint?

14 A From a clinical standpoint it would be the
15 existence of some set of arrhythmias caused by the
16 Digoxin itself.

17 Q Is it your opinion or your testimony here that
18 Digoxin toxicity is not defined by nonarrhythmic
19 symptoms?

20 MR. ERNST: Objection.

21 BY MS. AHERN:

22 Q It's a bad question, I apologize, and I'll
23 withdraw that one.

24 Is it your opinion that nausea and vomiting,
25 G.I. issues, those sorts of symptoms, visual

1 disturbances, are not clinical signs of toxicity?

2 A No, they are clinical signs, but they are not
3 necessary. They are not always present.

4 Q So you believe that you could -- a patient can
5 exhibit toxicity, skip through all those symptoms and go
6 right to life-threatening arrhythmias?

7 A Yes.

8 Q What do you base that opinion on?

9 A Well, I didn't really think about it, because
10 when I read all of this literature, and they talk about
11 the most common symptoms of toxicity, or any adverse
12 effect, they don't always mean that they are mandatory,
13 they have to show up before something occurs. The human
14 body is not that predictable.

15 And so in the last couple days I've been doing
16 a lot of research on this area. This is one of the
17 reasons I copied this article, because the statements
18 out of this article, and I need to follow up to make
19 sure what we're talking about, the gastrointestinal
20 symptoms occurred 30 to 70 percent of the time.

21 THE REPORTER: The symptoms occurred?

22 THE WITNESS: Let me start over again.

23 This article has a section of manifestations of
24 toxicity, and it describes nausea, vomiting, anorexia
25 and fatigue is probably the most consistent and most

1 frequently observed, extracardiac symptoms of toxicity.

2 But it goes on to say that it's, first of all, these
3 people are sick from many comorbid diseases. So a lot
4 of this can be confused in the mix.

5 BY MR. MORIARTY:

6 Q Masked?

7 A Masked. They cite, in articles that I have not
8 had a chance to follow through on that, the
9 gastrointestinal symptoms occurred in 30 to 70 percent
10 of patients with reported Dig toxicity.

11 Q Which article is this? I'm sorry.

12 A I just passed it away so I can't answer that.

13 Q This is "Mechanisms, Manifestations and
14 Management of Digoxin Toxicity in the Modern Era" by
15 Bauman, B-a-u-m-a-n?

16 A Yes.

17 Q In 2006. "Similar congenital cardiovascular
18 drugs"?

19 A So I just received your expert's opinions in
20 the last couple of days. I was -- that assertion was --
21 impressed me, and so I set about trying to find an
22 answer. Now --

23 Q So this is not information that you relied on
24 when you drafted your report?

25 A That's absolutely correct. I didn't consider

1 that there would be a necessity for those sorts of
2 symptoms prior to exhibiting toxicity.

3 Q Okay. And were you informed when you drafted
4 your report that all of the opinions that you had in
5 this litigation needed to be contained within your
6 report so that we come here today and ask you about
7 those?

8 A Well, yes. The problem with, you know, once I
9 read your doctors broadened my inquiry, because I hadn't
10 thought of it that way. I don't think, and will say
11 that I still do not think, that nausea and vomiting are
12 necessary in the diagnosis of Dig toxicity.

13 Q Okay. And this is, just to be clear, I'm
14 asking you specifically about what you knew and what you
15 relied on when you drafted your report which is dated
16 May 16th, 2011?

17 A When I --

18 Q This article that you just cited is not
19 something that you relied on, was it?

20 MR. ERNST: Let me clarify the record. The
21 defense has propounded four experts. Out of an
22 abundance of caution, I gave him those reports.

23 BY MS. AHERN:

24 Q That's fine. I'm not saying that there's not a
25 problem of you reviewing those reports --

1 MR. ERNST: It's the time for your deposition
2 today. I'm just presenting this witness to be as
3 complete as I can.

4 Many plaintiffs don't ever give their potential
5 experts their reports, and say they'll do it later. I'm
6 giving them to you, and gave it to him early so you'd
7 have the opportunity to ask him any questions you wanted
8 about that, and to make him as prepared as I possibly
9 could for this deposition.

10 MS. AHERN: And I do appreciate that, Don.

11 MR. ERNST: He's given you a report.

12 MS. AHERN: However, my questions right now are
13 very specific to the information that he relied on when
14 he actually drafted the report you submitted to the
15 defendants. We can get to that, but right now my
16 questions are about what he relied on prior to drafting
17 his report on May 16th, 2011.

18 MR. ERNST: I'm going to object.

19 THE WITNESS: Prior to drafting my report, I
20 did not think that it was a necessity that nausea, or
21 what do they call them, extracardiac symptoms related
22 were necessary in the diagnosis of Dig tox and toxicity.

23 BY MR. MORIARTY:

24 Q What information did you have at that time to
25 base that opinion on?

1 A Well, I've been at this -- I went to school in
2 the seventies. I graduated in 1980. I've been reading
3 these books and articles all along.

4 When they list adverse effects, they don't mean
5 that they are mandatory or necessary or absolutely will
6 show up.

7 In fact, some of the newer drugs that have come
8 on the market will actually have spreads of percentages
9 showing percentages of these side effects that appear in
10 patients. I couldn't find that in the last couple days
11 except in this article.

12 But my background assumptions were not the same
13 as the assertions by your experts. And so that's why I
14 went to look to see if they are right or I'm right.

15 Q Okay. And you believe that based on this
16 article that your assumption is correct, that Digoxin
17 toxicity does not progress along a continuum of
18 symptoms, but rather can skip ahead to life-threatening
19 arrhythmias prior to observing any other manifestations?

20 A Not exactly, because you've taken that one step
21 farther than I would have taken it.

22 It can be dose dependent, and I can guarantee
23 you that I could give you enough Dig to make you
24 nauseated.

25 Q In a situation where we're talking --

1 MR. ERNST: Let him finish answering his
2 question.

3 THE WITNESS: Whether you show up with an
4 arrhythmia because of that prior to or after the nausea,
5 I'm not too sure if the nausea needs to precede the
6 Digitalis's toxicity.

7 So the way I read your experts' reports is he
8 didn't suffer from Digitalis toxicity because there was
9 no nausea or vomiting reported. I'm oversimplifying, of
10 course. But I didn't think that was a necessary
11 predicate leading symptom.

12 Q Okay. And you mentioned dose dependent, that
13 you believe that this is dose dependent, your theory
14 that it can just progress to an arrhythmia rather than
15 having these noncardiac manifestations first; correct?

16 A It could. I haven't vetted this idea, because
17 it never came up in my mind when I wrote the report.

18 Q Okay.

19 A I still need to vet that in my mind.

20 Q But your thinking is that if you're given a
21 high enough dose of Digoxin, a patient can immediately
22 present symptoms of arrhythmia rather than all of these
23 other symptoms of nausea and vomiting and noncardiac
24 symptoms?

25 A It could happen is what I'm saying.

1 Q Do you have any opinion to a reasonable
2 probability what sort of dose a patient would have to
3 take for that to happen?

4 A No. I don't even know how you answer those
5 kinds of questions.

6 Q So it's your thought that you don't have
7 anything to support that yet?

8 MR. ERNST: Objection. That's not what he
9 said.

10 THE WITNESS: I'm not sure that that's the kind
11 of thing they do. I mean, they might have done, once
12 upon a time with rats, all of the symptoms showed up. I
13 don't know how you would tell if a rat was nauseated or
14 not. But there is -- I'm certain with almost all drugs
15 that I can give you enough to create a situation where a
16 lot of those adverse reactions will start to appear.
17 Now, whether or not they are going to appear in the same
18 order or certain doses or what, I don't know if that's
19 possible.

20 BY MS. AHERN:

21 Q Is it your opinion that Dan McCornack got a
22 massive overdose of Digoxin on the day that he died?

23 A A massive? No. I don't know what massive
24 means, though, so...

25 Q How much Digoxin do you think Dan McCornack

1 would had to have taken the day that he died in order to
2 exhibit --

3 A That's one of the reasons I put --

4 Q I just want to finish.

5 -- in order to exhibit a life-threatening
6 arrhythmia, and not all of these other noncardiac
7 symptoms?

8 A Because of the interpatient variability, it's
9 very difficult to make that assessment. So...

10 Q Would twice the amount of --

11 MR. ERNST: He's not done --

12 BY MR. MORIARTY:

13 Q -- of his normal dose?

14 MR. ERNST: -- answering the question.

15 THE WITNESS: The problem -- your question, I
16 mean, the problem is he's got Diltiazem on board and
17 some other antiarrhythmics, and the mix is just
18 unquantifiable.

19 BY MR. MORIARTY:

20 Q But I thought you said earlier that he was on
21 Diltiazem for a long enough period of time that whatever
22 effect Diltiazem had on the Dig levels would have been
23 stable for that period of time?

24 A It would have been. That's my assessment.

25 Q Right now we're only talking about the dose of

1 Digoxin altering that particular dose.

2 Would twice the dose, the daily dose, would
3 that have potentially put him at risk for a
4 life-threatening arrhythmia?

5 A I don't know if you can know that answer. See,
6 because these toxicities occur in all different kinds of
7 levels and concentrations, different settings or
8 sequences.

9 Q So, if Dan McCornack, for instance, had taken
10 1 milligram that day instead of .5, you can't tell me
11 whether or not that would have put him at risk for a
12 life-threatening arrhythmia?

13 A If he would have taken twice the daily amount I
14 would say, yeah, he would be in trouble.

15 Q Are you aware that in the past Dan had taken
16 1 milligram, he tolerated that?

17 A Yes.

18 Q Is there anything in the medical record of
19 you -- first of all, have you reviewed medical records?

20 A Yes, I have. Some.

21 Q Which medical records?

22 A The ones I've got --

23 Q I didn't notice it in your report, so I don't
24 know which ones you reviewed, and that was another one
25 of my questions, so we may as well hit it now.

1 A I think I cited them real early. No, I didn't.
2 I cite -- see, like I found the refill tracking form out
3 of one medical record. That's at cite number 3.

4 MR. ERNST: I think they are contained in the
5 depositions.

6 BY MS. AHERN:

7 Q Is it safe, then, to say that the only medical
8 records you reviewed were the medical records that may
9 have been attached as exhibits to the depositions that
10 you reviewed?

11 A I think that's probably true, yes.

12 Q So that's a fairly limited set of medical
13 records; correct?

14 A Yes.

15 MR. ERNST: Well, objection.

16 If you know.

17 BY MS. AHERN:

18 Q Do you know how many medical records --

19 A I know I looked at some medical records. Do I
20 know if they were complete or full? Yeah, I don't know
21 that. But I know I looked at some medical records.

22 Q Okay. And so it's from those medical records
23 you believe you are aware that Mr. McCornack had taken
24 up to 1 milligram per day of Digoxin in the past?

25 A I remember that being talked about.

1 Q That's twice the amount that he was taking when
2 he died; is that correct?

3 A Well --

4 MR. ERNST: Objection; vague as to time.

5 THE WITNESS: You're not assuming that he took
6 1 milligram for a sequence of doses, are you?

7 BY MS. AHERN:

8 Q I know that he took it for a couple of days.

9 MR. ERNST: Well, objection.

10 BY MS. AHERN:

11 Q So I'm asking would that put him at risk --

12 MR. ERNST: Objection. You're testifying.

13 THE WITNESS: Can I just --

14 BY MS. AHERN:

15 Q I'll ask you to assume that he took it. The
16 records say he took it for a couple of days.

17 A See, I thought the records said he only took it
18 for a couple doses, which would have been one day. Now
19 I didn't really zero in on that --

20 Q That's an interesting -- how many days do you
21 think a double the dose would have put him at risk for
22 life-threatening arrhythmia?

23 MR. ERNST: Objection; compound.

24 THE WITNESS: It's so patient specific, I don't
25 know if I can give you that answer exactly.

1 I would not, for instance, if he would have
2 called me and asked me, I would have said, Geez, please
3 don't do that, because any -- I mean, going over the
4 toxic level is somewhat more problematic for a person
5 taking it chronically, because they have large digitors,
6 and at some point it's dose dependent, true, and at some
7 point those arrhythmias are going to exhibit themselves.

8 I don't know if anybody can correlate when
9 those happen. You can't test humans, so nobody does it.
10 So I don't think that evidence is out there.

11 BY MS. AHERN:

12 Q Okay. You just testified, though, that you
13 thought that taking 1 milligram instead of .5 on the day
14 that he died might have put him at risk for
15 life-threatening arrhythmia?

16 A It might have, yes.

17 Q One day?

18 A Yes.

19 Q Any reason why it would not have put him at
20 risk for a life-threatening arrhythmia the year before
21 that?

22 A You know, I really didn't zero in on this.

23 MR. ERNST: Objection; vague as to time.

24 THE WITNESS: Was he on Diltiazem at the time?

25 See, maybe I misread that. I went over it very quickly,

1 but I thought he was not on Diltiazem at the time.

2 BY MR. MORIARTY:

3 Q So you think that the Diltiazem would have made
4 the difference --

5 A Yeah.

6 Q -- in your opinion?

7 A Oh, yeah.

8 Q Getting back to what your role was then, when
9 you wrote this report, was your role to determine
10 whether or not he had Digoxin toxicity prior to his
11 death?

12 A Mr. Ernst asked me to determine if there's
13 sufficient science to back up the opinions that the two
14 physicians that have opined that he suffered from
15 digitalis toxicity, and how that might come about. So
16 you have lots of factors that he didn't understand, and
17 postmortem redistribution. He told me about an article
18 or two, and so I'm trying -- I tried to work out all of
19 the different elements and factors that might have been
20 at play here on the night of this man's demise.

21 Q Do you recall from the depositions of the
22 physicians what they based their clinical, or what they
23 base their testimony that Dan McCornack might have
24 exhibited or might have had Digoxin toxicity at the time
25 that he died?

1 A I just don't remember. I'm sorry.

2 Q Those were clinical opinions, though; right?

3 A Those are their clinical opinions.

4 Q You were asked to find scientific support for
5 their clinical opinions?

6 A Yes.

7 Q What type of scientific opinions were you
8 asked to look for to support the clinical --

9 A The meaning of the 3.6 Dig level. If Mr. Ernst
10 is going to go to trial on this matter, he needs to be
11 able to know what that means and how it's going to be
12 used and what data it has in this case. Correct?

13 Q Okay. So your scientific support, what you
14 were looking at specifically is the postmortem Dig
15 level?

16 A Postmortem Dig level was a factor that I put
17 into the matrix to describe what might happen to
18 Mr. McCornack.

19 Q What were the other things that you put in the
20 matrix?

21 A Well, one of the things I thought was important
22 was the fact that he had 1.6 Dig level a year before
23 that was not a peak. The fact that he was on the
24 maximum dose of Diltiazem, and that he had been on this
25 rather consistently without a lot of other side effects,

1 if you will.

2 Q Did you review the records for Mr. McCornack
3 between the date that his 1.6 level was measured and the
4 date of his death?

5 A I don't think he went to the doctor a whole
6 bunch in those times.

7 Q So we don't have any medical records of what
8 was going on with his blood level at that time, do we?

9 A No.

10 Q So a lot could happen in ten months; right?

11 A Well, you know, a 40-year-old man doesn't
12 change in his physiology that greatly over a one-year
13 period.

14 Q Do you have the understanding of his underlying
15 medical conditions?

16 A Yes.

17 Q Do you have an understanding of the underlying
18 risks associated with those medical conditions?

19 A Oh, yeah. Like, for instance, he would take an
20 anticoagulant.

21 Q What were his underlying medical conditions?

22 A He had atrial arrhythmia. He also had some
23 other conditions, you know, from your experts they
24 describe him as obese. Off the top of my head, I can't
25 even remember. But those were all stated conditions,

1 not particularly stuff that I would think would be
2 transgressing or progressing. I don't know how to
3 explain or describe it best.

4 But I thought he was stable at the time that
5 the 1.6 was taken, and I thought he remained stable all
6 that year.

7 Q Do you have any understanding of the medical
8 progression of a chronic symptom like atrial
9 fibrillation in a young man?

10 MR. ERNST: Objection.

11 THE WITNESS: Some.

12 BY MS. AHERN:

13 Q What is the clinical significance of a
14 22-year-old man being diagnosed with atrial
15 fibrillation?

16 A The long-term effects, you know, the heart,
17 when it beats, tries to throw out all of the blood
18 without a lot of eddies and currents. So if the blood
19 eddies and currents, a clot can develop. So there's
20 this very nice symphony between the heart where it
21 almost leaves no blood in the ventricle. The atriums
22 are important in filling of those ventricles when this
23 whole process occurs.

24 One of the main problems, he should have been
25 on an anticoagulant. Even if he was to take an

1 anticoagulant -- he was taking an aspirin dose, but I
2 think that was the limit to which he was willing to
3 participate in that.

4 Q And the reason he should have been on an
5 anticoagulant, in your opinion, is because a person with
6 atrial fibrillation can throw a clot?

7 A Yes.

8 Q Is that fatal?

9 A It can be.

10 Q I have a few more questions about this.

11 You also mentioned earlier that it wasn't
12 really your job or your role here to determine whether
13 or not the tablets that Mr. McCornack took were actually
14 defective; is that correct?

15 A That's correct.

16 Q So your job is, basically, to determine if
17 there were formulation problems, if they actually
18 existed --

19 A Correct, somebody else --

20 Q -- could have caused Digoxin toxicity?

21 A Right. Somebody else is going to have to prove
22 they were defective.

23 Q If they are unable to prove that or if it is
24 shown that Dan McCornack's tablets were within
25 specification for bioavailability and everything else,

1 are your opinions valid anymore?

2 MR. ERNST: Objection.

3 THE WITNESS: My opinion would not be valid
4 probably.

5 BY MS. AHERN:

6 Q Okay. We've already talked, you're not a
7 medical doctor?

8 A No.

9 Q Not a cardiologist?

10 A No.

11 Q You're not a clinical pharmacologist?

12 A What's a clinical pharmacologist?

13 Q A clinical pharmacologist is actually a
14 specialty. Clinical speciality in pharmacology.

15 A That's a medical specialty. There is a group
16 of pharmacists known as clinical pharmacists.

17 Q Are you a clinical pharmacist?

18 A I served that role in the clinical pharmacist
19 school.

20 Q Are you a clinical toxicologist?

21 A Like I described, I'm not sure where that comes
22 in. I don't understand -- there's no profession for
23 toxicology. People have Ph.D.s with emphasis in
24 toxicology. People in pharmacy school study toxicology
25 and go into industry roles that involve toxicology.

1 Q You haven't done those?

2 A Toxicology is a part of the study of drugs.

3 Q You haven't done the specialties? You're not a
4 specialist in that area?

5 A No, I've not taken any additional training
6 other than pharmacy school and whatever continuing
7 education I might have had.

8 Q Do you consider yourself to be an expert in the
9 pharmacokinetics and pharmacodynamics of Digoxin?

10 A Well, it is part of the role of being a
11 pharmacist in a hospital today. If I couldn't say yes
12 to that, I'd probably be out of a job. Yes.

13 Q Okay. Thank you.

14 Have you published on pharmacokinetics or
15 pharmacodynamics of Digoxin?

16 A I've not published on it.

17 Q Have you done any further study on those topics
18 other than for the purpose of this case?

19 A No. I'm not the kind of -- when you use the
20 word "expert," what are you talking about? Am I a
21 university professor? No. Do I have a separate
22 research institute in which I deal with this subject?
23 No. What I am is a pharmacist that works in a community
24 hospital, and I do dosage estimates all of the time.
25 And I used what expertise I had to write this report.

1 Q Okay. Do you have any evidence at all that the
2 bioavailability of the Digitek that was recalled in 2008
3 was anything but what it was supposed to be according to
4 the FDA specifications?

5 MR. ERNST: Objection.

6 THE WITNESS: I'll have to defer on that.

7 BY MR. MORIARTY:

8 Q Do you have any evidence?

9 A I don't have any on me.

10 Q Have you seen any evidence that the
11 bioavailability of the Digitek that was recalled in 2008
12 was anything other than what the specifications said it
13 should be?

14 A I do not think I saw a bioavailability test. I
15 did not see a bioavailability test.

16 Q To some extent, is your opinion based on the
17 theory that bioavailability of Digoxin that
18 Mr. McCornack took was not within specification?

19 A Yes. I mean, Dig was -- is one of the drugs
20 with a narrow therapeutic index. And small changes can
21 result in changes in the therapeutic level. And it's
22 not an unknown equation, and it's been written about a
23 lot, and I've read it, that material.

24 Q Do you know when the last article on Digoxin
25 bioavailability studies was published?

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1 A It was probably a long time ago.

2 Q Do you know whether or not improvements were
3 made to bioavailability of all the Digoxin formulations
4 on the market or that they were standardized between the
5 time you read that last article and today?

6 A The problem is not so much whether or not you
7 can include the bioavailabilities. It's whether or not
8 the bioavailability changed. If there was a change in
9 the bioavailability, that would change the Dig level.
10 So let's say, for instance, there's a product out on the
11 market, for example, Phenytoin, has terrible
12 bioavailability and it's not a very good capsule, and
13 they've even renamed it as extended-release capsule.
14 Nobody will substitute generic Phenytoin for the
15 innovated product, because nobody wants to take the
16 chance that there's going to be a lack of levels or
17 increase in levels where a person has a seizure. So you
18 don't substitute those sorts of things.

19 It's the same thing with Digoxin. Normally the
20 first 15 years of my practice, I don't think I've ever
21 seen a pharmacist ever substitute Dig for a generic
22 medication, until Digitek came out on the market, which
23 surprised me, and people started substituting it, which
24 surprised me.

25 Q No offense, I'm going to move to strike the

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1 nonresponsive portion of that question.

2 How many different versions of Digoxin are on
3 the market?

4 A That, I don't know.

5 Q Are you aware that there are more than one
6 generic version of Digoxin on the market?

7 A I believe there is.

8 Q Ballpark figure, do you know how many?

9 A No. I work in a hospital. So I don't know.

10 Q To what extent do you think your opinions on
11 the subject of bioavailability of Digitek are influenced
12 by your training in pharmacy school?

13 A Heavily. I mean, bioavailability is an issue
14 whenever pharmacists decide to substitute. And
15 substitution in California is something that pharmacists
16 do.

17 Q But you haven't done any independent research
18 on that particular issue as far as it pertains to
19 Digoxin since pharmacy school?

20 A Correct.

21 Q And I have a couple of other questions.

22 A Your last question excludes this endeavor on my
23 part?

24 Q Excluding the litigation, yes.

25 A Okay.

1 Q When we're talking about pharmacokinetics of a
2 drug you define steady state, so does Gilman and
3 Goodman, as the time at which the amount of drug put
4 into the body is equal to the amount being secreted by
5 the body?

6 A Right.

7 Q So we have an equilibrium?

8 A Approximately. You understand it's really an
9 osmotic thing. So five to seven times a halflife,
10 you're at about 90 percent. So, you know, when you
11 start to look at other factors, when you start to get
12 tests, there's errors in the tests and there's all sorts
13 of other factors. So 90 percent is usually described as
14 a steady state. The assumptions are kind of sort of
15 made that it's not going to go up anymore.

16 Q What's not going to go up?

17 A Well, because osmotically approach is 100
18 percent, some theoretical maximum; right? So what --
19 the math is that at five to seven times a halflife,
20 you're 90 percent there.

21 Q I'm just asking about steady state in lay terms
22 so the jury can understand this concept.

23 A In lay terms they would be the intake equals
24 the out.

25 Q Gotcha.

1 We're not talking about it, but what's defined
2 is that there's a store of Digoxin in the body that
3 remains theoretically equal or steady as more is being
4 added and as the drug is being excreted?

5 A Correct. So you don't go down to zero.

6 Q Correct.

7 A You start at some higher level.

8 Q The point is to maintain a certain level in the
9 active site; correct?

10 A Hopefully.

11 Q It takes about seven to ten days to reach
12 steady state with Digoxin, doesn't it?

13 MR. ERNST: Objection.

14 MS. AHERN: Excuse me?

15 THE WITNESS: The question was, does it take
16 seven to ten days to reach steady state?

17 MR. ERNST: Objection.

18 BY MS. AHERN:

19 Q For a normal person receiving Digoxin it takes
20 approximately seven to ten days to reach steady state;
21 correct?

22 A I am so tired that I thought that the halflife
23 of Digoxin was 24, 30 hours, something like that. So
24 five to seven times, yeah.

25 Q Okay. Seven to ten?

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1 A That's just in the label, I believe. Right.

2 Q Do you agree that it would take seven to ten
3 days for a patient to achieve a new steady state level
4 if their dose was changed?

5 A A new steady state level, yes. Not a momentary
6 passing.

7 Q Right. A single double dose in one day, which
8 patients sometimes will take, is not going to affect
9 your overall steady state level?

10 A It won't affect your steady state level, but it
11 will produce a peak and will result in the next trough
12 to be higher than the previous troughs.

13 Q Is that more or less important with drugs that
14 have a long halflife?

15 A Well, a long halflife, it is probably not as
16 important, yeah.

17 Q Okay.

18 A I mean...

19 Q Digoxin has a relatively long halflife, doesn't
20 it?

21 A The problem that you're not putting in that
22 equation is the therapeutic index. So, if you have say
23 Ampicillin, which has a large therapy index, there's a
24 huge margin for error there. So if you're off by
25 different percentages, it's just not going to be of any

1 moment. But when you have a narrow therapeutic index,
2 it's kind of like threading a needle through a hole. So
3 it takes a lot less to move in that very specific small
4 area.

5 Q Do you have an opinion to a reasonable degree
6 of probability as to how much defective tablets
7 Daniel McCornack would have to ingest and over what
8 period of time in order to actually change his steady
9 state level?

10 MR. ERNST: Objection; asked and answered.

11 Go ahead and answer the question.

12 THE WITNESS: Well, a steady state for him
13 would have probably been achieved in seven to ten days.
14 So, you know, if you are asking me did he get a steady
15 state level, then it would be five to seven times the
16 halflife. You're asking me if his blood levels were
17 encroached or pass over that area of which he would
18 start to exhibit toxic effects, it depends upon the
19 starting position he's at, where that line is that I --
20 where the line is that you can't cross to start the
21 toxic effects, could be, and it is not all that uncommon
22 to find patients start to exhibit toxic symptoms on the
23 upslope as those peaks and troughs start to increase.

24 BY MS. AHERN:

25 Q Have you done any calculations in this case to

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1 determine what effect --

2 A I have not done physical calculations.

3 Q To determine how many tablets --

4 A Right.

5 Q -- Mr. McCornack would have taken and how
6 many --

7 A Given the time --

8 Q -- days?

9 A -- time restraints that I was given to write
10 this report, I did not think it was particularly
11 fruitful nor all that probative. So I elected just to
12 use Global RPH to essentially demonstrate the concept.

13 Q The Global RPH is this table we have --

14 A Correct.

15 Q -- on -- this is the table on page 4?

16 A I believe so. Yes.

17 Q Okay. So on here we have increase in
18 bioavailability of up to 50 percent?

19 A Correct.

20 Q Okay. And we know that he's taken at least up
21 to 100 percent on occasion?

22 MR. ERNST: Well, objection. Objection as to
23 time.

24 THE WITNESS: Well, once in the past I think I
25 read that he reported that he had taken a double tablet.

1 And I don't -- see, my recollection of it is that it was
2 a sporadic thing, not a consistent thing and that he
3 reported that he felt bad he took a double tablet in
4 those days and he was counseled against it. That's
5 very, very long ago. And I -- so that's all I know
6 about that.

7 BY MS. AHERN:

8 Q Okay.

9 A It was really deep in the medical record, as I
10 remember.

11 Q Just looking at your table here, I'm sure you
12 can probably do it in your head; if not, I can
13 understand, I can't do in my head anymore.

14 If you increased the bioavailability or if you
15 doubled the dose in this case, so you have 100-percent
16 increase in bioavailability, what would his steady state
17 level be?

18 A I guess you could do like we used to do in
19 school before we had computers. I mean, if 50 percent
20 took you from 2.4 to 1.6, is that a .6 difference? No.

21 MR. ERNST: .8.

22 THE WITNESS: .8 difference. Thank you very
23 much.

24 BY MS. AHERN:

25 Q So we would be up to, what, 3.2?

1 A Is it linear? I don't know if it's linear.

2 We're assuming it's linear. You ever do that --

3 probably too young. The biorhythmic tables --

4 Q I remember those.

5 A -- where you tried to extrapolate on two. That

6 was based on the idea that the error, you were doing it

7 linear and you're not on the curve, the error was so

8 minute that it was not important.

9 Q Is there any reason you didn't go ahead and
10 have Global RPH calculate increased bioavailability all
11 of the way up to 100 percent in terms of determining
12 steady state level?

13 A I wasn't trying to say that it increased the
14 bioavailability. I was just trying to give the lay of
15 the land. Whether you're trying to determine what's the
16 magnitude of these effects, I was kind of using this as
17 the -- to show what you might expect if that was to
18 happen.

19 Now, the reason I picked zero to 50 was
20 because, in my mind, I kind of used 80 percent as the
21 benchmark for Dig. And if a new formulation comes
22 along, it would be an increase of about 20 percent. If
23 some of the literature says it's 60 to 80, so 40 to 140.
24 So I was trying to get in those ranges to give you a
25 feel for what the increases might be looking like.

1 Q Okay. You can never have more than 100 percent
2 bioavailability; right?

3 A I hope not.

4 Q If we have a tablet that's absorbed up to
5 80 percent, 80-percent bioavailability, we're really
6 looking at this 20-percent increase in bioavailability?

7 A Well --

8 Q To get to 100 percent?

9 A Yes. So these are increases. So we're
10 talking --

11 Q So at 100 percent bioavailablity in a tablet,
12 am I correct in looking at your table here, starting at
13 with the level of 1.6 with Dan McCornack?

14 A My thinking process was that if it was 60 plus
15 40 it would 100. Then I just included one data point
16 past.

17 Q Okay. I'm just -- maybe I'm looking at this
18 differently now. But am I correct that you started with
19 1.6 because that's a level that we had on Mr. McCornack
20 ten months prior to his death; correct?

21 A Right. What I did was set it in the Global RPH
22 to get the coefficient and the constants so I could make
23 these changes. Then I went through the program and
24 started changing the dose. And I wanted to include a
25 20-percent increase and a 40-percent increase, and I put

1 one past that for reference frame.

2 Q Okay.

3 A Just for the insight.

4 Q We assume, then, that for Mr. McCornack, his
5 tablets, you know, were 60-percent bioavailable for
6 Digoxin?

7 A Somewhere around 60 to 80 is what I would --

8 Q He had a level of 1.6. If we increase that to
9 100 percent, his maximum level would be somewhere around
10 2.24?

11 A Correct.

12 MR. ERNST: Objection.

13 MS. AHERN: You've made your objection.

14 Q If we've assumed -- you've answered the
15 question; right? That's what this is basically getting
16 at?

17 A Right, but you're playing numbers now.

18 Q I am, because you have numbers in here. I'm
19 asking you about the numbers in your report.

20 A Right. And I didn't give these numbers to be
21 exact numbers --

22 Q I understand.

23 A -- so you can extrapolate --

24 Q I totally understand. And I am exploring --

25 MR. ERNST: Let him finish answering his

1 question.

2 BY MS. AHERN:

3 Q -- how this works.

4 A I'm trying to show you what the lay of the land
5 would be.

6 Q Okay.

7 A The problem is that you don't really know with
8 just one data point if you have the correct coefficient
9 or not.

10 Q I agree. One doesn't tell me much.

11 A No. And the 1.6, you know, assuming in an
12 all-perfect world that it was, he is the one person who
13 sits directly on the line and is not one of the
14 outliers, and this is what it would be.

15 Q Okay.

16 A But he could potentially be one of the
17 outliers. So that's the clinical decisions that makes
18 it difficult when you're adjusting doses. You can't
19 just play with numbers.

20 Q I understand.

21 I'm going to follow through with my questions
22 on this table so that we can understand exactly what. I
23 know this is theoretical. Right? It's a theoretical
24 calculation?

25 A It's based on the perfect person that fits the

1 equation.

2 Q Right. And we don't know if McCornack was the
3 perfect person.

4 So theoretically then, if we --

5 MR. ERNST: I would like to take a short break.
6 You are talking as quickly as an auctioneer, and that's
7 a compliment, okay.

8 MS. AHERN: We're going to finish my question
9 before and then we can take a break.

10 MR. ERNST: Actually, we can take a break at
11 any time.

12 MS. AHERN: There's a question pending, and it
13 is highly inappropriate for you to go out --

14 (Interruption by the reporter.)

15 MR. ERNST: Is there a question pending?

16 (Interruption by the reporter.)

17 THE WITNESS: If there's a partial question, it
18 is proper to have that question answered before we take
19 a break, so go ahead.

20 MS. AHERN: I believe there was a proper
21 question pending as well.

22 (Record read.)

23 MS. AHERN: We've already acknowledged on the
24 record that this is theoretical.

25 MR. ERNST: I just --

1 MS. AHERN: I can talk very slowly if you would
2 like. If that's the problem, I can speak very slowly.

3 THE REPORTER: I do need you to slow down.

4 MR. ERNST: What I would like to do is to take
5 literally a three-minute break. Three-minute break is
6 all I request. If you'd like to finish asking this
7 question I thought it was partitioned in any way, that's
8 fine, if you want to take a shot at it. If not, I'd
9 like a three-minute break.

10 MS. AHERN: I would like to finish my question.
11 I only have one on this. We've already asked the first
12 part of it.

13 MR. MORIARTY: Let's stop debating and ask the
14 question.

15 BY MS. AHERN:

16 Q The question is, we have already assumed that
17 if we had a bioavailability in the tablet that
18 Mr. McCornack took of 60 percent --

19 A Uh-huh.

20 Q -- if we go up to 100-percent bioavailability,
21 we have a level of about 2.24 for his steady state
22 level? Understanding this is theoretical level.

23 MR. ERNST: Objection. Multiple objections.
24 Go ahead.

25 MS. AHERN: I will give you a standing

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1 objection on this line of questioning if you'd like, if
2 you just stop interrupting me so we can get through
3 this.

4 Q The next question I had was, if the
5 bioavailability was 80 percent for the tablet he took,
6 and we added 20 to get to 100-percent bioavailability,
7 that puts him at a steady state zero Digoxin
8 concentration of about 1.92; correct?

9 MR. ERNST: Objection.

10 THE WITNESS: If he's the perfect man.

11 BY MS. AHERN:

12 Q If he's the perfect man.

13 And 1.92 is within the therapeutic range;
14 correct?

15 A It's lower than the toxic range.

16 MS. AHERN: Now if you want to take your
17 three-minute break before I finish up, we can do that.

18 MR. ERNST: That would be great.

19 (Recess.)

20 BY MS. AHERN:

21 Q Mr. Gibson, we've been talking about blood
22 levels all day; right?

23 A We have.

24 Q Or serum levels?

25 A Or serum levels, yes.

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1 Q I wanted to ask, where is Digoxin
2 pharmacological activity? Is it in blood or is it in
3 tissue?

4 A It's in tissue.

5 Q So are you aware that there are calculations
6 that you can perform to determine the approximate tissue
7 concentrations of Digoxin of a person taking that drug?

8 A From the tissue?

9 Q Uh-huh. There are calculations you can perform
10 to determine the tissue concentrations of Digoxin?

11 A From blood levels?

12 Q From the dose and from other parameters?

13 A Yes. No.

14 Q Okay. So you're not aware of any calculations?

15 A I'm not familiar with that.

16 Q Okay. You're not aware of any software
17 available that would allow a person to calculate both
18 blood concentration and tissue concentrations in an
19 individual based on their own physiological parameters
20 and the dose they are taking?

21 A There are pharmacokinetic programs where you
22 can put in all of those variables, and they will give
23 you expected. I never saw tissues though. But I don't
24 know anybody that would ask that Dig levels in heart
25 blood cells. I've never seen that. But we do have

1 programs that I use regularly for both vancomycin and
2 gentamicin to do just what you're asking.

3 Q Okay.

4 A But --

5 Q I'll represent to you that there are programs
6 and there are algorithms that one could use to calculate
7 the different compartments, the different concentrations
8 of Digoxin the various body compartments?

9 A I'm not aware. Now I will go look for them.

10 Q Do you think that it would be important with a
11 drug like Digoxin which has effect on cardiac tissue to
12 know what the actual tissue concentrations of the drug
13 are at any point in time?

14 MR. ERNST: Objection.

15 THE WITNESS: I didn't even think that it was
16 all that valuable to calculate them in this particular
17 case just to get serum levels, because there are too
18 many variables that could occur in a person. I mean, I
19 think the clinical picture is probably the telling
20 aspect of this. So, no, I didn't.

21 BY MS. AHERN:

22 Q Okay.

23 A It didn't cross my mind. I don't know what I
24 want to say. I didn't think it was all that
25 appropriate.

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1 Q Okay. And we talked a little bit today about
2 we have some articles discussing this passive diffusion
3 of the Digoxin from tissues into the blood postmortem.
4 Would it be important or relevant to know what a tissue
5 concentration was so you could have an understanding of
6 the gradient and where that gradient --

7 A Yes. Yes. I didn't mean to imply that not
8 knowing that there are these uptake mechanisms or that
9 you do have certain tissues with concentrations of Dig
10 that are varying in the blood. I didn't mean to imply
11 that I didn't know that or those didn't exist. I just,
12 what I think was focusing was on the ability to
13 calculate that. That's the part that I was --

14 Q Okay.

15 A -- not too sure. I've never seen anybody
16 calculate those kind of things.

17 Q You've cited in here an article -- I don't know
18 if it was Goodman or not? Sorry. I think it was
19 Gilman.

20 A Goodman and Gilman.

21 Q 42, cite 42. That at steady state the
22 concentration of Digoxin in cardiac tissue is about 15
23 to 30 times higher than that of plasma?

24 A Correct.

25 Q So we know the tissue concentration of the drug

1 is significantly higher than that we find in blood?

2 A Correct.

3 Q That would be important to know in terms of
4 what your gradient is postmortem for passive diffusion?

5 A That's kind of been the assumption all morning.
6 That we're talking about a gradient from the blood
7 that's closest to the heart to what would be in the
8 distal parts of the body.

9 Q But knowing the value of that would give you a
10 better idea of where you are in that gradient, in that
11 process of diffusion; correct?

12 A Correct.

13 Q Also knowing the timing of his last dose would
14 also be very important. Obviously, you know where you
15 are in that process?

16 A Have you ever timed passive distributions for
17 an osmotic effect?

18 Q Have you?

19 A I've done it in an in-vitro situation.

20 Q In-vitro?

21 A It's very slow.

22 Q Yes, it is. But we're talking about tissue and
23 human blood.

24 Do you have any frame of reference for the time
25 on that?

1 A Well, the difference in tissue and blood is
2 once a person dies, all the active processes -- well,
3 some of the active processes die and the other active
4 processes die slowly as the patient dies.

5 Then you have to wait for the breakdown to
6 occur. So there's a breakdown of the cells before they
7 can release the contents. So it's not just passive
8 redistribution straight up like in-vitro, for instance.
9 But it's not very fast.

10 MS. AHERN: I think that's all I have right
11 now.

12 MR. MORIARTY: I've got about five minutes'
13 worth of questions.

14 MR. ERNST: Well, I'll have some more
15 questions. I think it's my turn.

16 MR. MORIARTY: I think you actually get to go
17 last. But if you want to ask your questions, you go
18 ahead and then I'll go last.

19 MR. ERNST: I'll tell you what, if you want to
20 ask your questions and you won't ask other questions
21 after I ask my questions, that will be fine.

22 MR. MORIARTY: Can't promise that.

23 MR. ERNST: Then it's my turn.

24 MR. MORIARTY: Go ahead.

25 Note a continuing line of objection to any

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1 questions he asks at a discovery deposition of his own
2 expert.

3 Go ahead.

4 MR. ERNST: Not to be in violation of pretrial
5 order 22, why would you object to my asking an expert
6 questions at his own deposition?

7 MR. MORIARTY: That isn't a PTO 22 objection.

8

9 EXAMINATION

10

11 BY MR. ERNST:

12 Q Good afternoon, Mr. Gibson.

13 A Good afternoon.

14 Q We've been in your deposition for approximately
15 five hours at this point?

16 A Yes, we have.

17 Q And you've indicated you are a little tired?

18 A I -- yes.

19 Q But we will try and speak slowly and cover some
20 ground here.

21 In your report dated May 16th, 2011, you put in
22 50 footnotes and 12 other references for a total of 62
23 specific references in your report?

24 A That's correct.

25 Q And you reviewed all of this material to give

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1 your best testimony as to the Digoxin issues that have
2 been presented in this case as they related to
3 Mr. McCornack?

4 A Yes.

5 Q Now, there have been a number of questions
6 asked about all of the articles that have been presented
7 to you. And many of them, the questions were selected
8 with a specific quote to a specific sentence in a 10- or
9 15- or 20-page article; true?

10 A True.

11 Q And have any of the questions changed any
12 opinion that you have related in your report dated
13 May 16th, 2011?

14 A No, they have not.

15 Q For instance, in Exhibit D, you were asked --
16 MR. MORIARTY: Which one is that?

17 MR. ERNST: The Koren report, spelled
18 K-o-r-e-n. "Postmortem Redistribution of Digoxin in
19 Rats."

20 Q Mr. Moriarty asked you if a specific sentence
21 were true, but he didn't read all of the sentences or
22 the paragraph; true?

23 A As I remember.

24 Q For instance, one of the questions was, quote,
25 "In common with early reported human studies, the first

1 part of our experiment indicates that in the rat low
2 antemortem serum levels during life tend to increase
3 significantly after death."

4 He asked you if that were true. And you stated
5 that he read it correctly.

6 But he did not read you the next sentence,
7 which is, "On the other hand, this phenomenon was not
8 observed following exposure of test animals to higher
9 Digoxin dosage." Is that also true?

10 A That is true.

11 Q For instance, he went to the conclusion and
12 picked up the one item, item two, where he talked about
13 antemortem Digoxin intoxication cannot be reliably
14 inferred on the basis of high-dose mortem levels on the
15 drug alone.

16 But he did say that Digoxin -- or item 3 also
17 reads, "Digoxin intoxication can be ruled out when
18 postmortem serum concentrations remain within the
19 therapeutic range." Do you see that?

20 A Yes.

21 Q In this particular case, the test of
22 Mr. McCornack came back at 3.6; true?

23 A Yes.

24 Q And that is not in the therapeutic range?

25 A That is not in the therapeutic range.

1 Q And therefore you cannot rule out Digoxin
2 intoxication?

3 A You cannot rule out Digoxin intoxication.

4 Q And he left out item one, which reads, quote,
5 "After death passive redistribution of Digoxin may take
6 place when the serum concentrations are within the
7 therapeutic or toxic range it appears likely that
8 Digoxin will reenter the blood," period.

9 But he left off "High antemortem serum
10 concentrations of Digoxin may prevent such a passive
11 redistribution"; true?

12 A True.

13 Q Now, as an example, is this whole series of
14 quotes that would appear to you to be taken in isolation
15 and in many cases out of context?

16 A Yeah. There's some out of context, yeah.

17 Q Now, I --

18 A I mean the problem with out-of-context things
19 is that they can be true statements. True statements as
20 to the context in which they were given and related to
21 the case study that they are talking about. For
22 instance, I think at one point I was asked -- or about
23 some statements said you just cannot consider postmortem
24 Dig levels at all for anything. I don't think that's
25 true. I think you can consider them for some stuff. I

1 think they do tell you and they do give you some data.
2 But what you do with that, though, I don't think you can
3 extrapolate back based on one point. But they do tell
4 you that he had consumed Dig and that he consumed a
5 fairly large amount of Dig.

6 Q So going back to your report, which I believe
7 has been marked as Exhibit A --

8 A I believe so.

9 Q -- in this deposition. Is everything in that
10 report true and accurate to your knowledge?

11 A Yes, I believe everything in there is --

12 Q And --

13 A -- true.

14 Q And if there were someone saying that you were
15 not qualified to testify at an OFAIR hearing, would you
16 have said in your report is sum and substance of what
17 you intend to testify at the time of trial?

18 A That's correct.

19 Q And I have a couple of more specific questions.
20 Does the pharmaceutical evidence that you have
21 in this case, together with all of the reading, support
22 the opinions and conclusions of Dr. Mason that
23 Dan McCornack died of Digoxin toxicity?

24 A They do.

25 Q And is that your opinion?

1 A That's my opinion.

2 Q Tell us why you believe that Dan McCornack died
3 of Digoxin toxicity.

4 A Well, I believe that he was taking a
5 substantial dose, .25 twice a day. He was taking it in
6 the morning and evening. He was also on Diltiazem,
7 which has been known to raise the Dig levels. I believe
8 his doctor had every intention of treating this as
9 aggressively as possible. They wanted his levels to be
10 high. The postmortem level is one data point, but the
11 other more important data point, I believe, is the 1.6
12 that was taken a year before, and what I believe to be a
13 fasting level. So that would be a trough and not a
14 peak. And so I think when you talk about these levels
15 always being most consistently related to the peaks, I
16 believe that he was at the very edge of Dig toxicity and
17 that's what the doctors wanted him to be. They believed
18 that was the appropriate treatment for him, for his
19 arrhythmias.

20 Then something came along that changed the
21 amount of Dig that Mr. McCornack -- one of the
22 possibilities is -- well, I mean there's lots of
23 possibilities. But if this company produced
24 nonconforming tablets, it's a very strong possibility
25 that Mr. McCornack, if he were to consume those, would

1 have had a new Dig level which might have pushed him
2 over the -- conditional words are difficult for
3 nonscientists. Scientists always use conditional terms
4 and I'm trying not to be conditional -- but would push
5 him over that level in which he went into toxic
6 morbidity.

7 Q Is it your opinion that more likely than not,
8 after the review of all of the material that you have
9 reviewed in this case, that the elevated Digoxin level
10 in Mr. McCornack caused his arrhythmia and his death?

11 A That's what I think happened.

12 Q And based upon a number of items that you have
13 reviewed, including defendants' Exhibit 92, which is
14 Mr. Bliesner's report?

15 A Yes.

16 Q Now, in that report, although you didn't
17 read -- well, in that report, looking at item 22, which
18 I think you pointed out, it notes in that June of 2004,
19 there was a complaint from a pharmacist in Bellingham,
20 Washington regarding a thick Digoxin tablet. And
21 confirms double thickness, and no definitive root of
22 cause found. Compression occurred on tablet pressed
23 number 67 or 71. Tablet manufacture occurred six,
24 seven, ten November, 2003. No chemical testing
25 conducted on the product. And this is the first

1 instance of a double-thick Digoxin tablet reportedly
2 confirmed in the marketplace. Do you recall reading
3 that?

4 A Yes.

5 Q Is that an anomaly?

6 A That's an anomaly. One of the reasons I
7 pointed it out to you, I read a case study where the
8 problem was a change or a variation in the lubricant
9 that was put into the Dig tablet and that resulted in
10 tablets sticking to the presses. So I pointed that out
11 to you in order to alert you to the idea that there
12 might have been a formulary issue, formulation issue
13 with these Digoxin tablets.

14 Q And there's also a reference, item 39 -- sorry,
15 strike my previous question.

16 Item 39 in Dr. Glide's report indicates on the
17 30th of November, 2007 double-thick tablets discovered
18 during the manufacture of Digoxin 0.125 milligram
19 tablets. Although initially halted, production
20 continued following only visual inspection. Detailed
21 investigation conducted within a very short period of
22 time. The product is released to market without
23 conclusive evidence of what caused the double-thick
24 problems on 5 December, 2007. No chemical testing of
25 tablets was conducted.

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1 Do you recall reading that?

2 A I recall reading that, pointing it out to you,
3 yes.

4 Q Why did you point that out to me and why did
5 does it bother you?

6 A Well, it bothers me because it tends to
7 indicate that there was a formulation issue at this
8 manufacturer. I mean, it kind of looks like when you
9 review that report that these people had very poor
10 quality control. And if they are having tablets that
11 are double pressed, I don't see how you can just reject
12 them as anomalies and release that product. I think you
13 need to examine and discern why the double pressing
14 occurred other than why it was sticking in the machine.
15 I think bioavailability of the test needed to be done.
16 I didn't see any of that done by the manufacturer.

17 Q Do you see a note from the FDA dated 18th of
18 March to 20th of May, 2008, wherein they actually
19 comment on the complete lack of the quality control
20 system in the production of Digitek?

21 A I did see that in the report, yes.

22 Q And that bothered you, as well, as a
23 pharmacist?

24 A It sure did. If there's anything that a
25 pharmacist or doctor relies on is the absolute certainty

1 that the product they are dispensing meets certain
2 standards for which they can make their clinical
3 judgments therefrom.

4 Q And I take it that this is the kind of
5 nonconforming tablet that has been demonstrated in the
6 reports by Actavis itself and confirmed by the FDA that
7 you believe were more likely true than not the reason
8 for Mr. McCornack's --

9 A Demise.

10 Q -- demise?

11 MR. MORIARTY: Objection.

12 MS. AHERN: Objection.

13 BY MR. ERNST:

14 Q Is that true?

15 A Yeah. I -- his clinical picture is absolutely
16 stable. Something new happened on this particular date.
17 You can look for sort of reasons that are sort of out
18 there, but I mean, when you combine that with the known
19 data that he had a high Dig level postmortem, I mean, he
20 was taking quite a bit of Dig. But something was
21 different about that time for Mr. McCornack.

22 Q And in all of the things that you reviewed, all
23 of the things, is it your opinion it's more likely true
24 or not it was a nonconforming Digitek tablet or tablets?

25 A I believe so.

1 Q And for the record, I believe you testified to
2 this, but if there is a Digitek tablet that is a double
3 strength -- double-strength dose, that is possible to
4 cause toxicity in an individual like Dan McCornack?

5 A Depends upon where my starting position is and
6 how close I am to the toxic level, yes, it could be.

7 Q Now, you recall that his wife on the -- at the
8 time on the day of his death reported that he was
9 fatigued and felt bloated?

10 A I do you recall that.

11 Q What does that mean to you?

12 A Well, fatigue is --

13 MR. MORIARTY: Objection.

14 MS. AHERN: Objection.

15 THE WITNESS: Fatigue is one of the symptoms of
16 Dig toxicity. But the problem with it is it's going to
17 be masked by so many other people. People who have
18 atrial fib can just be fatigued as a natural course of
19 illness.

20 BY MR. ERNST:

21 Q And I think you've answered this question, but
22 is it necessary that there be nausea or vomiting before
23 Digoxin toxicity manifests itself in the heart?

24 A I do not -- at this point in my research I did
25 not, when I wrote the report, believe that was a

1 necessary symptom that would precede cardiac arrest.

2 Q And the Digitek level that was taken on
3 Mr. McCornack after his death was 3.6; true?

4 A Yes.

5 Q And in light of all of the other information
6 that you had in this case, all of the articles that
7 you've read, what does that 3.6 level mean to you?

8 A To me it means that he had a substantial amount
9 of Digoxin on board and that there probably is some
10 redistribution occurring, because of that it's a data
11 point that I think needs to be considered in looking at
12 the final clinical picture of Mr. McCornack.

13 Q Now, is it safe to say that you can't
14 extrapolate back to the exact number at the time of his
15 death as to what the Digitek level would have been?

16 A I cannot extrapolate back to the exact numbers,
17 correct.

18 Q But it is your opinion that the 3.6 postmortem
19 level of Digitek --

20 A Digoxin.

21 Q -- Digoxin in his blood serum level is an
22 indication of a toxic level in his body at the time of
23 his death?

24 A I think that is correct.

25 Q And in Dr. Bliesner's report, item 38 referred

1 to an October 1st, 2007, internal e-mail with Actavis
2 indicating that Digoxin .25 milligram is the top product
3 where adverse drug effects were associated with death or
4 permanent injury.

5 Do you recall pointing that out to me?

6 A I do, but -- yes.

7 MR. ERNST: All right. Thank you. I don't
8 have any other questions at this time.

9

10 FURTHER EXAMINATION

11

12 BY MR. MORIARTY:

13 Q In the course of your work as a pharmacist,
14 have you ever read an Establishment Inspection Report?

15 A No.

16 Q Have you ever read a warning letter?

17 A No.

18 Q Have you ever read an FDA form 483?

19 A No.

20 Q In your work as a consultant in this case, did
21 you read any 483s, warning letters or EIRs?

22 A If I did, I wouldn't know they were 483s or
23 EIRs.

24 Q Okay.

25 A If I read them, I just read them, I didn't pay

1 much attention to form.

2 Q So when Mr. Ernst was pointing out something in
3 David Bliesner's report about a lack of quality control,
4 do you know whether the underlying document actually
5 says that about Digitek production?

6 A All I know is what was in that report.

7 Q Do you know whether the batch that Mr. Ernst
8 was talking about in November of 2007 was of the same
9 dose strength as prescribed to Mr. McCornack?

10 A All I know is what's in that report.

11 Q Do you know whether that was the batch that was
12 referred to in Exhibit F -- the MDL Exhibit 38, the FDA
13 statement I read to you before?

14 A No, I don't.

15 Q Do you know anything at all about the 2004
16 single double-thick tablet incident that Mr. Ernst asked
17 you about?

18 A No. My role was --

19 Q Do you know what the FDA's reaction was when
20 Actavis reported that to them?

21 A I don't know what FDA's reaction was.

22 Q Outside this litigation consultation, have you
23 ever been asked to address a scientific value of a
24 postmortem blood concentration?

25 A No.

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1 Q Do you have that Dr. Gallanter's article that
2 you pulled a couple days ago?

3 A You want my copy?

4 Q Yep. It's the only copy in the room.

5 A Do you know what it looks like? Would it be
6 quicker for you to find it than me?

7 Q The Beauman Gallanter article.

8 A Can you recognize it from the front?

9 MS. AHERN: Here. Maybe -- I'll take a look if
10 you don't mind.

11 MR. MORIARTY: Why doesn't Hunter look at it
12 while I finish asking you some questions.

13 Q When you read the actual reports of
14 Dr. McMaster, Gallanter, Heard and Brown, I know you may
15 disagree with their opinions, but did you find any
16 particular scientific flaws in their reasoning?

17 MR. ERNST: Objection.

18 THE WITNESS: They all -- they all didn't
19 address -- if I was to summarize what I got from those,
20 was that they were assessing different causes of death
21 other than Dig toxicity, and none of them seemed to
22 address the issue of whether or not the tablet was
23 conforming or nonconforming. Is that what you're
24 asking? Did I?

25 ///

1 BY MR. MORIARTY:

2 Q Well, you're inviting editorial comment, so I
3 will skip it.

4 A All right.

5 Did you find it?

6 MS. AHERN: I didn't. It may be in your other
7 ones.

8 THE WITNESS: Okay.

9 BY MR. MORIARTY:

10 Q What percentage of --

11 A I know I had it.

12 Q -- of patients -- what percentage of patients
13 will skip the prodromal symptoms and go straight to
14 life-threatening emergencies?

15 A See, I cannot --

16 Q I'm sorry, life-threatening arrhythmias?

17 A I can't answer that right at this point.

18 Q Do you know whether it's more than 50 percent?

19 A I don't know.

20 Q Is it more likely than not that patients will
21 have prodromal symptoms before going to life-threatening
22 arrhythmias?

23 A The majority of patients do report nausea and
24 vomiting. That is the most common report.

25 Q Okay. How long have you known Don Ernst?

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1 A Twenty years. I mean he's --

2 Q You have to answer. You can't --

3 A Oh, sorry.

4 Q -- ask him for confirmation.

5 Are you -- do you see him at San Luis Obispo
6 Bar Association meetings?

7 A I don't typically go to the standard bar
8 meetings. I go to criminal defense bar section
9 meetings. So I don't see him there.

10 Q Okay.

11 A And he has been a fixture in and out of the San
12 Luis Obispo court as long as I can remember.

13 Q Has he ever tried a case against you?

14 A Oh, no.

15 Q Have you ever tried a case together where he
16 had one defendant and you had another?

17 A Oh, no.

18 Q Have you ever referred him a case?

19 A Um, I referred cases to the law firm of Ernst &
20 Mattison.

21 Q Okay. And have you -- has he ever referred any
22 case to you?

23 A I doubt it because my legal practice is limited
24 to my practice as a public defender, and except for that
25 one year in which I tried to do some family law I

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1 generally do not take any cases.

2 Q Have you and Mr. Ernst ever socialized
3 together?

4 A Oh, no.

5 Q Never had a drink together, never had lunch
6 together?

7 A Other than in prep for this, like today and
8 stuff, no.

9 Q Okay. Related by blood or marriage to
10 Mr. Ernst?

11 A No.

12 Q And how have you known him for 20 years?

13 A Well, I mean, he's had a law firm in this town,
14 and when you are in court as often as I am, which is
15 almost daily, he comes to court. And I see him in the
16 hallway. We've talked casually. I don't have a
17 relationship with Mr. Ernst that would be one in which I
18 go to his house, he hasn't come to my house, that kind
19 of thing. I've never seen him socially anywhere. But
20 he is one of the prominent lawyers in the community.
21 I've never referred a case to him as a referral fee or
22 anything like that. It's just the casual, Who do you
23 know that does that? There's a guy across the street.

24 Q Did you find the article in your materials?

25 A No.

1 Q It's an article by Beauman, so-and-so and
2 Gallanter. You gave it to him because it was written by
3 one of my experts?

4 MS. AHERN: He is one I asked you about. The
5 one you got last night.

6 THE WITNESS: The one I got last night?

7 MS. AHERN: I believe.

8 MR. MORIARTY: There it is.

9 (Defendants' Exhibit J was marked for
10 identification.)

11 BY MR. MORIARTY:

12 Q So I've marked Exhibit J. This is the article
13 you got last night; right?

14 A Yes.

15 Q And you read it?

16 A Most of it, yes.

17 Q Did you find it reasonable?

18 A Yeah.

19 Q Is it the kind of material you would have
20 footnoted had you read it prior to writing your report?

21 A I probably would have checked a few of the
22 references before I -- but, yes.

23 Q Okay.

24 A I mean there's nothing wrong with the article.
25 I had very little time with it last night. And I found

1 it to be something that I needed to follow through on.

2 Q And so far as the meaning of a postmortem level
3 of 3.6 as was drawn under these circumstances, for that
4 would you defer to the opinion of a Ph.D. toxicologist
5 who has prior experience in that area?

6 MR. ERNST: As opposed to?

7 THE WITNESS: Having my own opinion.

8 BY MR. MORIARTY:

9 Q As opposed to you having absolutely no prior
10 experience in it?

11 A I mean, I don't think I need to defer.

12 MR. MORIARTY: Okay. That's all I have.

13 THE WITNESS: You've been typing like crazy so.

14 MR. ERNST: Okay.

15

16 FURTHER EXAMINATION

17

18 BY MS. AHERN:

19 Q I just have a couple questions and they are not
20 big ones. I just wanted to ask some specifics about
21 that.

22 You mentioned a case study where there were
23 tablets sticking to presses because of the change of
24 lubricant used in formulation?

25 A Yeah. You know, I've been trying to find that.

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1 I read somewhere in the past, and I haven't been able --
2 I've been looking for it for a while.

3 Q Is it something that you knew maybe since
4 pharmacy school?

5 A I thought it was in an old textbook, so I've
6 been trying to find it to get the exact case and
7 description and stuff.

8 Q Do you remember what drug it was at issue?

9 A It was Dig.

10 Q It was Dig?

11 A And --

12 Q We're talking --

13 A I didn't include it in the report because I
14 couldn't refind it, but I did mention it to Mr. Ernst
15 when he asked me about manufacture whether I reviewed
16 that report that he was going over, and so I -- I
17 mentioned it at that time. Here's some things that you
18 need to look at and consider.

19 Q Okay. Did you have any information from
20 Mr. Ernst or anybody that there were issues with tablets
21 sticking to presses with the Digitek that was recalled?

22 A What I was trying to tell Mr. Ernst is that
23 tablets sticking sometimes is a symptom of change in
24 formulary.

25 Q Did you understand at the time that there was

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1 issues with tablets sticking?

2 A I heard that.

3 Q With Digitek?

4 A I heard that. It would probably be
5 double-pressed tablets. When the press comes down and
6 presses them, the tablet doesn't pop out. And
7 essentially that's the function of the lubricant in
8 there, to keep it from sticking to the metal pieces. So
9 when the next tablet comes it compresses. So I
10 mentioned to him that this is an area of inquiry that
11 you can follow through on.

12 Q Where did you get information about tablets
13 being double pressed? Why was it your understanding
14 that that was the issue in this litigation?

15 A I think it was in that -- who is that doctor?

16 Q Bliesner's report?

17 A Yes. I could be wrong.

18 Q So your understanding --

19 A Plus there was discussion between lawyers with
20 me about just generalities when I started. And that's
21 where I heard it.

22 Q Okay. And so to some extent did that form your
23 opinions or how you approached this project?

24 A Yes. I mean, essentially, maybe I'm wrong
25 here, but if there is a malfunctioning tablet, in my

1 mind, in other words, if Mr. McCornack died from
2 digitalis toxicity and no malfunctioning tablet, it's --
3 there's no case, right?

4 Q Well, I'm just asking about how you got
5 information about the particular defect here that you're
6 describing, this double-compressed tablet. I just don't
7 know where you found that information.

8 A When they charged me to do this, I'm asking
9 things like, Why would you charge me to do this? What
10 is the sorts of stuff that you've heard? And what are
11 you thinking and why are you going in this direction?
12 To me, that would -- pressed tablets is the symptom of
13 the formulation having some difficulties.

14 Q Did you see any double-thick tablets or double
15 pressed --

16 A I've never seen double-thick tablets.

17 Q I want to finish so she doesn't get mad at us.
18 Have you ever seen double-thick tablets,
19 double-thick Digitek tablets in your career?

20 A No.

21 Q Did you see any double-thick tablets in
22 Daniel McCornack's remaining unused tablets?

23 A I didn't look at all of them. I at the time --
24 you'll have to excuse me. Allergies.

25 Q Do you need some water?

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1 A At the time I didn't know what the case was
2 about. When I looked at the tablet, the idea was are
3 these Digitek and do I have a case? Do I have a Digitek
4 case?

5 Q So you were just asked in terms of product
6 identify issue?

7 A When I looked at the tablets.

8 Q You weren't inspecting them at all for their
9 appearance, thickness?

10 A I was not.

11 MR. ERNST: I should tell you for the record, I
12 think he might have been consulted in 2008. There may
13 be an e-mail out there that I've been looking for. So
14 if I find it, I will ship it to you guys.

15 THE WITNESS: Sorry.

16 MS. AHERN: Okay. That's all.

17 MR. MORIARTY: I'm sorry. Now I have one more.

18 MR. ERNST: Matt Moriarty, you would not be
19 Matt Moriarty if you just didn't have one more question.

20

21 FURTHER EXAMINATION

22

23 BY MR. MORIARTY:

24 Q When do you believe you first told Mr. Ernst
25 that this bioavailability issue was something you were

1 thinking about? 2008, 2009, 2010? Recently?

2 A Probably more recently. There was a long
3 period that I didn't hear anything from Mr. Ernst, so...

4 Q Okay.

5 A I didn't know the case was proceeding.

6 MR. MORIARTY: Okay.

7 THE WITNESS: I knew they called me in, said
8 this is the next step, and they'd like to proceed in
9 this direction.

10 MR. MORIARTY: I'm done.

11 You know about signature? You have the right
12 to either read and sign this and correct it for errors
13 or you can waive that. It's up to you.

14 MR. ERNST: Have it sent to you.

15 THE WITNESS: Okay.

16 MR. ERNST: And sent to him personally.

17 Did you guys bring a check for him today?

18 MR. MORIARTY: Nobody asked me to.

19 MR. ERNST: Come on, Matt.

20 MR. MORIARTY: Nobody asked me to.

21 MR. ERNST: It is the custom to bring a check
22 at the time of the expert's deposition.

23 MR. MORIARTY: That may be the custom here, but
24 not where I live or where -- how I practice in this
25 business. So he's more than welcome to send a bill

1 directly to me and I will submit it for payment.

2 MR. ERNST: And the time you would expect to be
3 paid?

4 MR. MORIARTY: From 9:00 a.m. to --

5 MR. ERNST: No, I mean, oftentimes, different
6 people pay bills differently. I would like the bill
7 paid promptly. Will you assure me the bill will be paid
8 promptly?

9 MR. MORIARTY: I will submit it, and if it
10 isn't prompt enough for Mr. Gibson, he can call my
11 office or you can call me.

12 MR. ERNST: Fine.

13 MR. MORIARTY: What you're essentially asking
14 me to do is pay his bill out of the law firm as opposed
15 to submitting it to the client for payment?

16 MR. ERNST: It is our habit and custom to do
17 that. I realize you're from Cleveland so we will do
18 this. We will submit a bill.

19 Do we have an agreement as to the time?

20 MR. MORIARTY: It's 3:12 in the afternoon. Is
21 that what you're asking me?

22 MR. ERNST: I am. Six and a quarter hours are
23 acceptable to you?

24 MR. MORIARTY: Sure.

25 MR. ERNST: Okay.

1 MR. MORIARTY: I'm ordering this transcript
2 rough -- I mean rush. If -- when I get it, I'm sending
3 it to my experts. If he hasn't read and signed it by
4 then, sobeit. You can quiz my experts all you want on
5 whether there's a mistake on the transcript. I don't
6 really care how long he takes to read and sign it.

7 MR. ERNST: Okay. Historically what we do here
8 is that we ship it out and give the deponent 30 days to
9 read and sign it. But whatever you choose to do is
10 okay. You have every right to have a rush transcript or
11 even a rush transcript and submit it to your experts.

12 MR. MORIARTY: He can have 30 days to read and
13 sign it.

14 MS. AHERN: One thing, Mr. Gibson's e-mail has
15 changed. Do you want to attach it as an exhibit or do
16 you want to put it on the record?

17 THE WITNESS: My e-mail's on the report.

18 MS. AHERN: It's no big deal.

19 MR. MORIARTY: I don't intend to e-mail you so
20 I don't care what your e-mail is.

21 MS. AHERN: That's what I was thinking.

22 MR. ERNST: Are we clear we can sign this under
23 penalty of perjury? Is that agreeable with you,
24 Counsel?

25 MS. AHERN: Yeah.

1 MR. ERNST: He can sign this deposition
2 transcript under penalty of perjury.

3 MR. MORIARTY: He was sworn. He knows what the
4 law is. If he's committed perjury, he's already
5 committed perjury. His signature has nothing to do with
6 that.

7 MR. ERNST: Well, actually in California, what
8 happens is he has to come to the court reporter's
9 offices unless we agree that it can be sent to his
10 residence for him to read it and sign it in the confines
11 of his residence.

12 MR. MORIARTY: He can read it in and sign it in
13 the confines of his residence, his law office, his
14 pharmacy office, his ALJ office. I don't care where he
15 reads and signs it. He doesn't have to come here to
16 this court reporter's office.

17 MR. ERNST: Thank you, Counsel.

18 (Deposition concluded at 3:15 p.m.)
19
20
21
22
23
24
25

REPORTER'S CERTIFICATE

I, Cindy D. Griffith, a Certified Shorthand Reporter in and for the State of California, do hereby certify:

That, prior to being examined, the witness named in the foregoing proceeding was by me sworn to tell the truth, the whole truth and nothing but the truth.

That said deposition was taken before me at the time and place therein set forth and was taken down by me in shorthand and thereafter reduced to computerized transcription. I hereby certify that the foregoing deposition is a full, true and correct transcript of my shorthand notes so taken.

Dated at San Luis Obispo, California, this 16th day of June, 2011.

CINDY D. GRIFFITH
CERTIFIED SHORTHAND REPORTER

Keith Patrick Gibson

June 14, 2011

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT NO. 36073

CASE NAME: Digitek Products Liability Litigation

DATE OF DEPOSITION: June 14, 2011

WITNESS' NAME: Keith Patrick Gibson

In accordance with the Rules of Civil Procedure,
I have read the entire transcript of my testimony or it
has been read to me.

I have made no changes to the testimony as
transcribed by the court reporter.

Date Keith Patrick Gibson

Sworn to and subscribed before me, a Notary Public in
and for the State and County, the referenced witness did
personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing sworn Statement; and
Their execution of this Statement is of their free
act and deed.

I have affixed my name and official seal this _____
day of _____, 20____.

Notary Public

Commission Expiration Date

Keith Patrick Gibson

June 14, 2011

1 DEPOSITION REVIEW

CERTIFICATION OF WITNESS

2

ASSIGNMENT NO. 36073

3 CASE NAME: Digitek Products Liability Litigation

DATE OF DEPOSITION: June 14, 2011

4 WITNESS' NAME: Keith Patrick Gibson

5 In accordance with the Rules of Civil Procedure,
6 I have read the entire transcript of my testimony or it
has been read to me.

7 I have listed my changes on the attached Errata
8 Sheet, listing page and line numbers as well as the reason(s)
for the change(s).

9 I request that these changes be entered as part of the
10 record of my testimony.

11 I have executed the Errata Sheet, as well as this
12 Certificate, and request and authorize that both be appended
to the transcript of my testimony and be incorporated therein.

13

Date Keith Patrick Gibson

14

15 Sworn to and subscribed before me, a Notary Public in
and for the State and County, the referenced witness did
16 personally appear and acknowledge that:

17

They have read the transcript;

18 They have listed all of their corrections in the
appended Errata Sheet

19 They signed the foregoing sworn Statement; and

20 Their execution of this Statement is of their free
act and deed.

21 I have affixed my name and official seal this _____
day of _____, 20____.

22

Notary Public

23

24

Commission Expiration Date

25

(888) 391-3376

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